FLUKE®
Biomedical

Medical Equipment Quality Assurance:
Inspection Program Development and Procedures

J. Tobey Clark
Director, Instrumentation & Technical Service,
Faculty, Biomedical Engineering/School of Engineering

Michael Lane
Associate Director, Instrumentation & Technical Services

Leah Rafuse
Clinical Engineer, Instrumentation & Technical Services

The UNIVERSITY of VERMONT

Instrumentation & Technical Services
University of Vermont
280 East Avenue, Suite 2
Burlington, VT 05401

FLUKE®
Biomedical

Chapter 1: **Introduction** 2

Chapter 2: **Definitions** 3

Chapter 3: **Using a Risk-Based Assessment for Establishing a Medical Equipment Maintenance Program** 5

Chapter 4: **General Procedures** 11

Chapter 5: **Electrical Safety** 24

Chapter 6: **Equipment Inspection Procedures** 37

General Equipment 38
Apnea Monitor 41
Aspirator 45
Cardiac Output Unit 49
Central Station Monitoring System 52
Compression Unit 55
Defibrillator 59
Electrocardiograph 65
Electrosurgical Unit 69
Enteral Feeding Pump 73
External Pacemaker 77
Fetal Monitor 80
Hypo/Hyperthermia Unit 84
Infant Incubator 88
Infusion Pump 94
Non-Invasive Blood Pressure Monitor 99
Patient Monitor 103
PCA Pump 110
Phototherapy Unit 116
Pneumatic Tourniquet 119
Pulse Oximeter 123
Radiant Warmer 127
Sphygmomanometer 131
Therapeutic Stimulator 134
Therapeutic Ultrasound 137
Ventilator 141

Appendix 1: **Standards** 147

IEC 60601-1 147
IEC 62353 147
NFPA 99 148
The Joint Commission 148

CHAPTER 1: Introduction

The purpose of this document is to provide guidance in establishing and managing a medical equipment quality assurance (QA) program and to present detailed procedures for inspection, preventive maintenance, safety evaluation, and performance testing.

The target audiences for this publication are those responsible for establishing and managing medical equipment QA program, and staff performing inspections and device testing. Readers should have a basic technical background and some exposure to medical equipment in healthcare. The book does not provide background information on clinical or technical concepts or medical equipment principles of operation.

Medical equipment QA is part of an overall medical equipment management program for a healthcare facility or system. A complete program also includes corrective maintenance or repair, equipment control, asset management, health care technology planning, education, and activities directed toward improving medical device-related patient safety.

The publication is organized into four primary sections:

- A glossary of terms
- Background information on establishing and managing a program including goals, methods, device inclusion and rating criteria, and standards
- General and device-specific procedures and forms for inspection, preventive maintenance, safety evaluation, and performance testing
- An appendix with reference information

Forms, tables, diagrams, illustrations, and photos are used to aid in the understanding of the content.

The publication takes into consideration the advances in device reliability, reduced preventive maintenance requirements, and internal device surveillance (self test) along with changes in standards. Due to the ongoing efforts at global harmonization, international standards are used and referenced where applicable, such as electrical safety testing references IEC 62353.

Acknowledgements
The publication was funded by a grant from Fluke Electronics Corporation (FEC). A number of diagrams, illustrations and figures were provided by FEC as was test equipment used in many of the photographs.

CHAPTER 2: Definitions

A meaningful preventive maintenance program requires consistent terminology. This section contains practical definitions of terms used in this manual.

Adverse event: Sometimes referred to as a device incident. An event or circumstance arising during care that could have or did lead to unintended or unexpected harm, loss, or damage.

Calibration: The process of determining the accuracy of a device by comparing it to a known measurement standard. The device is then adjusted to agree with the standard within a recommended tolerance. Minor adjustments to achieve the specified accuracy are considered part of the calibration process. Major readjustments and parts replacement are considered repairs and are not included in the calibration process.

Class I medical equipment: Electrical medical equipment with accessible conductive parts or internal conductive parts protectively grounded in addition to basic insulation.

Class II medical equipment: Electrical medical equipment that uses double insulation or reinforced insulation for protection against electric shock in addition to basic insulation.

Clinical equipment: Medical equipment used for diagnosis, treatment, or monitoring of a patient. Clinical equipment is further broken down to life-support and non-life-support equipment.

Clinical risk: The risk associated with the clinical use of the equipment, taking into account how invasive the equipment is to the patient.

Corrective maintenance: Also known as repair. Corrective maintenance entails isolating the cause of the device failure. Affected components are adjusted or replaced to restore normal function. A performance inspection is performed following corrective maintenance before the device is placed back into service to ensure proper operation of the device.

Device inclusion: How a device is used determines whether or not to include the device on the managed inventory. The device inclusion categories include clinical equipment, utilities equipment, and general equipment. Most equipment on the inventory will be classified as clinical equipment.

Electrical safety testing: Testing of equipment to assure it is electrically sound to avoid the possibility of microshock. Electrical safety testing involves testing the ground wire resistance, current leakage to the chassis, and current leakage to the patient leads.

Equipment inventory: A record of medical equipment used in a facility. The inventory may include equipment that does not receive scheduled maintenance as well as managed equipment for tracking purposes.

Estimated time: The estimated amount of time needed to perform the scheduled maintenance. The estimated time includes the time from test set up to the conclusion of the maintenance.

Exception testing: Following scheduled performance inspections, only failures are documented. Equipment that has not been documented as needing repair or adjustment is assumed to be safe and ready for use. This method of testing is useful when performing preventive maintenance and performance inspections on a large number of devices.

General equipment: Equipment that cannot be classified as either clinical or utilities equipment.

Incoming inspection: A performance test performed on a piece of medical equipment before being put into use to verify the safety of the device.

Life support equipment: Medical equipment that takes over a function of the human body and whose loss will cause immediate death.

Maintenance interval: Also referred to as testing frequency or the length between scheduled maintenance. Most commonly, the maintenance interval is given as a length of time (i.e. every 6 months), but can also be given in hours of equipment operation (i.e. every 10,000 hours).

Managed inventory: A record of medical equipment used in the facility that only includes equipment requiring scheduled maintenance.

Mean time between failures: The average time between failures of a device or system. This is used as an indication of reliability.

Nosocomial infection: An infection contracted by a patient during a hospital stay.

Performance inspection: A procedure to ensure a device operates appropriately. The device should meet safety and performance requirements of regulatory agencies, the healthcare facility, and the manufacturer. Performance inspections will vary by device type and each device type should have a written procedure that includes the characteristics that are tested, how to test them, and acceptable operational limits. Performance inspections are performed periodically to ensure proper operation of devices prior to being put into service for the first time, after a repair, or anytime the operation of the device is questioned.

Physical risk: The risk associated with device failure.

Preventive maintenance (PM): Periodic procedures to reduce the risk of device failure. The maintenance interval may be based on time (e.g. every 12 months) or operational usage (e.g. every 1,000 hours). Preventive maintenance is designed to ensure continuous operation of equipment. Preventive maintenance tasks may include replacing parts, lubricating, and adjusting. Preventive maintenance excludes tasks normally carried out by the user.

Problem avoidance probability: The likelihood of a device to fail, based on historic data related to medical equipment repair and maintenance.

Procedure: Maintenance tasks that need to be completed for effective performance testing and preventive maintenance.

Quality assurance: A systematic process of checking to see whether a product or service is meeting specified requirements.

Regulatory requirements: Specific criteria that must be met as set forth in codes and standards. Regulatory requirements often have the power of law behind them from a governing body.

Repair: Also known as Corrective Maintenance. Entails isolating the cause of the device failure and replacing or adjusting affected components to restore normal function. A performance inspection is performed following corrective maintenance before the device is placed back into service to ensure proper operation of the device.

Risk assessment: The identification and quantification of possible hazards. A risk assessment involves a numerical scoring system to quantify the amount of risk.

Risk management: A process by which possible hazards are identified and assessed. Procedures are put into place to minimize the risks from the identified hazards.

Standards: Also referred to as codes. Guideline documentation of practices agreed upon by industrial, professional, or governmental organizations. The standard will usually establish a specific value used for evaluation compliance with the standard.

Utilities equipment: Equipment that supports medical equipment, life support, infection control, environmental, communication, or critical utility systems.

User checks: Also known as operator checks. Performance checks on medical equipment that can be performed by the clinical user. These are often simple operational checks that do not require the use of tools or test equipment.

FLUKE®
Biomedical

CHAPTER 3: Using a risk-based assessment for establishing a medical equipment maintenance program

Goals of the maintenance program

The goal of any medical equipment maintenance program is to **ensure that medical equipment is safe, accurate, and ready for patient use**. Quality assurance is achieved with periodic checks of the equipment. The purpose of establishing risk-based maintenance intervals is to provide high-quality, cost-effective inspections based on risk and function, historical data on problems found, and the effect of maintenance on the reduction of problems.

The PM/Inspection procedures should be based on need that includes the maintenance requirements of the device, risk classification, device function, and history of incidents. Maintenance and performance inspections do not prevent random failures, particularly related to electronic equipment and low risk devices do not need performance verification at the same frequency or intensity of higher risk devices.

Medical equipment should be evaluated to determine how often testing should be performed. If a device is not tested often enough, it may fail before the next scheduled maintenance or give erroneous results. If a device is tested too frequently, time that could be better spent maintaining other equipment is wasted. The biomedical professional's job is to achieve a balance between the time and effort needed for periodic functional testing and the safe use of medical equipment.

Risk-based inspection intervals

In order to maintain an efficient maintenance program, the frequency of inspection must be determined. Effort should be spent on equipment where testing is likely to have an impact on the continued safe operation of the medical device.

The University of Vermont has developed a risk-based system for determining the maintenance frequency. Intervals are established for equipment inspection based on risk, requirements, logistics, and history. Written criteria are used to identify risks associated with medical equipment per the **Maintenance Strategy Worksheet**. The risks include equipment function, physical risks associated with use, and equipment history as it relates to patient safety. Life support equipment is specifically identified and receives the highest priority for actions.

The risk criterion is divided into five categories: clinical function, physical risk, problem avoidance probability, incident history, and regulatory or manufacturer requirements. Devices are given a score for each of these categories. The scores for each category are added up and a total score is given for each device type. Maintenance strategies are determined based on the total score. A combined score of 13 or more is justification for semiannual testing, a score of 9–12 is justification for annual testing, and a score of 8 or less is justification for less than annual testing, either bi-annual or no scheduled testing, depending on clinical application. The result is a more cost-effective test program that will result in improved patient care through less equipment downtime and more dollars for direct patient care activities.

The risks identified are used to assist in determining the strategies for maintenance, testing, and inspection of medical equipment. In addition, the identified risks are used to guide the development of training and education programs for staff that use or maintain equipment. All medical equipment is screened at the time of delivery and appropriate training and testing of new equipment takes place prior to use on patients.

The risk assessment should be done for each new device type during the incoming inspection when the device is added to the inventory. The device will then have a testing frequency assigned. After this is done, the maintenance history of the device should be monitored in order to evaluate the effectiveness of the maintenance program. The process is shown in Figure 1.

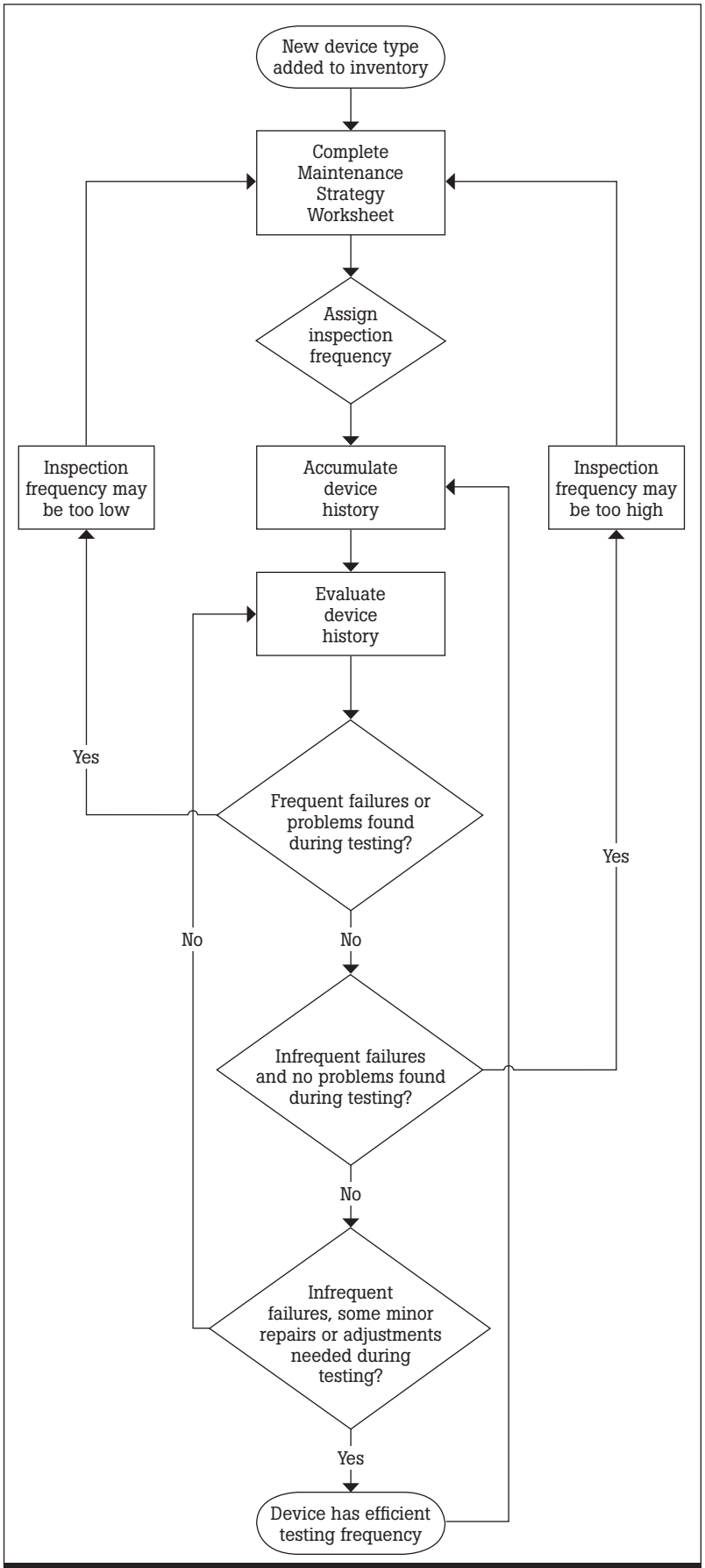


Figure 1.

 ©University of Vermont, Rev. 2 – Confidential

FLUKE®
Biomedical

Maintenance strategy worksheet

Rating system for risk-based inspections

University of Vermont Technical Services Program

Most device types have been evaluated and classified for test frequency already.
For new device types, use the scoring system to evaluate the frequency of testing.

Criteria: Choose one rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	
There are requirements for testing independent of a numerical rating system	2	
Total Score:		
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		

A combined score of 13 or more is justification for semiannual testing.
A combined score of 9–12 is justification for annual testing.
A combined score of 8 or less is justification for less than annual testing (either bi-annual or no scheduled testing, depending on clinical application).
Anesthesia machines and vaporizers are recommended for testing three times per year.
Some blood delivery devices such as warmers may be required to be tested four times per year based on AABB or CAP requirements.

Maintenance strategy assignment

Maintenance Program	Check	Ends	Comment
Warranty: Attach coverage			
Full manufacturers service contract			
Manufacturers service contract with first look by TSP			
CAPP contract with first look by TSP			
TSP scheduled maintenance and repair			
Hospital scheduled maintenance and repair			
TSP repair on failure only			
User maintenance only			
Replace on failure only			

Completed by: _____ **Date:** _____

Clinical function is how invasive the equipment is to the patient. At the low end of this category is a device that does not make patient contact, for example, an exam light. The high end of this category is a device used for life support, such as a ventilator.

Physical risk is an evaluation of what will be the outcome if the device fails. At the low end is low risk; failure is more of an inconvenience than actual harm such as an otoscope. Failure of this type of device does not pose a threat to the patient's outcome and the clinician can easily use an alternate device with little impact to patient care. At the high end is severe injury or death of the patient such as ventilator. Failure of this type of equipment can have a serious detrimental effect on the patient's outcome.

Problem avoidance probability is based on historic data related to medical equipment repair and maintenance. The low end of this category is maintenance or inspection having no impact on the reliability of the device; the high end is common device failures are predictable and can be avoided by preventive maintenance. This category also has an additional level, specific regulatory or manufacturer's requirements that dictate preventive maintenance or testing.

The device incident history is also based on historic data. This category only has two scores, and is answered as yes or no. If a device had a history of being involved in an incident resulting in patient harm, the device would score high. Otherwise, the device would score low.

The last category is **manufacturer's or regulatory requirements**. This is also either yes or no. If the device has a specific requirement for maintenance or testing, the device would score high, otherwise the device would score low. The chart shown gives the scores from the maintenance strategy worksheet for a few medical devices.

To illustrate the application of the Maintenance Strategy Worksheet, two examples are given below, outlining the use of the worksheet. The first example is the pulse oximeter; the second is the electrosurgical unit.

The pulse oximeter is a device used for non-invasive monitoring of blood oxygen levels. The clinical function category would score 3 because the device is used for direct patient monitoring. Physical risk would score 3 because failure of the device would cause inappropriate therapy, perhaps not giving the patient supplemental oxygen, and/or loss of monitoring. Problem avoidance would score 2. Historically speaking, failures of pulse oximeters are unpredictable and impending problems are usually not uncovered during periodic testing. Both incident history and manufacturer/regulatory requirements score 1. Historic data does not show a history of incidents involving pulse oximeters and there are no specific requirements for maintenance of these devices. This gives the pulse oximeter a total score of 10. Based in the maintenance worksheet, this is justification for annual testing.

Device Type	Clinical Function	Physical Risk	Problem Avoidance Probability	Incident History	Manufacturer or Regulatory Requirements	Total Score	Testing Frequency
Ventilator	5	4	4	2	2	17	Semiannual
Electrosurgical unit	4	4	2	2	1	13	Semiannual
Infusion pump	4	3	2	2	1	12	Annual
Pulse oximeter	3	3	2	1	1	10	Annual
Exam table	2	2	2	1	1	8	Bi-annual

 ©University of Vermont, Rev. 2 – Confidential

The electrosurgical unit is a device that uses high-frequency electric current for cutting or destroying tissue. The clinical function category would score 4 because the device is used for direct treatment of the patient. Physical risk would score 4 because failure of the device could cause severe injury to the patient. Problem avoidance would score 2. Historically speaking, failures of electrosurgical units are unpredictable and impending problems are usually not uncovered during periodic testing. Incident history would score 2. Historical data reveals that electrosurgical units have been involved with patient incidents. Manufacturer/regulatory requirements would score 1, as there are no specific requirements for maintenance of these devices. This gives the electrosurgical unit a total score of 13. Based in the maintenance worksheet, this is justification for semiannual testing.

As it can be seen from the previous examples, devices that have more risk associated with them need more maintenance than other devices. In the example, electrosurgical units will receive maintenance twice per year based on a risk assessment, while pulse oximeters will receive maintenance once per year.

One should note that devices were scored as generic device type only and are not model-specific. The risk criterion is used as a tool for determining maintenance intervals. If a specific model has testing or maintenance requirements different from other devices of the same type, the maintenance schedule can be adjusted on a case-by-case basis.

Evaluating the effectiveness of the maintenance program

Every maintenance program should be periodically evaluated for effectiveness. Performance standards for medical equipment management should support the efforts of hospitals to manage health care technology for the purpose of improving the quality of care, containing the cost of health care delivery, and improving the safety of patients, hospital staff, and visitors. Tracking device histories is useful for evaluating the effectiveness of the maintenance program. A computerized system is especially useful for this task, as different types of equipment problems will need to be tracked.

Maintenance inspection intervals should be reviewed annually, to make changes as justified, as well as following any changes in regulations or guidelines. The review is done by analyzing the data generated from the maintenance history. To facilitate analysis, coding in the computerized maintenance management system on the types of problems encountered is required. The University of Vermont uses a system where a work order is generated for every maintenance event of a device. The work orders are coded by type of maintenance event and the work order types categorize the service performed. Work order types for maintenance, user errors, no problem found, recalls, upgrades, and other risk categories are tracked through the equipment problem summaries. These summaries are available for reporting to the Safety Committee to improve patient care and create a safe environment.

Devices that frequently have problems found during the periodic performance inspection or that have a high failure rate in between inspections may need to have more frequent inspections. Likewise, as the reliability of medical devices improves, fewer problems are found during functional testing. In addition, newer technology often requires fewer scheduled parts for replacement as electronic controls are replacing mechanical systems. For example, anesthesia machines are beginning to use electronically-controlled flow controls instead of the traditionally used mechanical needle valve assemblies. Electronically controlled devices tend to be more accurate and do not have parts that wear like mechanical systems do. These devices may no longer continue to benefit from frequent inspections.

In addition to tracking problems found during functional testing, other types of device problems should be tracked. Device problems that cannot be reproduced and perceived problems arising from incorrect use are indicators that clinical staffs need additional education on the proper use of these devices. For example, if it is noticed that there is a high incidence of work orders with no problems found for patient monitors, the clinical staff may need to be retrained on the proper operation of the monitors. Devices that have been abused may indicate the need for additional staff education or a change in clinical protocol such as equipment storage or cleaning. Device failures that could have been prevented with proper maintenance, such as tubing and filters that need to be changed in a ventilator indicate that the maintenance schedule should be reevaluated or that additional technical education is needed.

Performance standards should be clear and reasonable, as well as ensure that local regulations are met. The most obvious example of a performance standard is the functional testing completion rate. The University of Vermont has found a realistic goal for the functional test completion rate is 95 % of clinical devices with 100 % of life support devices. Other performance standards should be developed, such as the number of use error related problems and damaged devices.

If an evaluation finds the goals are not met, an action plan should be developed to address the problems. The underling cause of the problem must be discovered and then steps to solve the problem must be taken. After a plan has been implemented, the plan should be monitored to determine progress and evaluate whether or not the plan was effective.

CHAPTER 4: General procedures

Inventory control

Understanding what devices are in the facility in order to provide a quality maintenance program is critical. Inventory data is used for a variety of applications including establishing a maintenance schedule, tracking medical device hazards and recalls, and deciding when to replace aging equipment.

Using a computerized medical equipment management system

A computerized medical equipment management system is a useful tool in keeping track of the device inventory and maintenance history. There are several programs commercially available, but whatever software is chosen, the following information should be tracked.

Basic device information: Any medical equipment management software should track basic device information. At a minimum, the device type, manufacturer, model, and serial number should be tracked. This information is essential to the maintenance program.

Clinical use: The clinical use of a device should be documented. Equipment used for life support needs to be given a higher priority for maintenance. Additionally, regulations on life support devices may be different. In the United States, the Joint Commission requires equipment used for life support to have a 100 % completion rate for scheduled maintenance.

Location: This may be entered as the owner department or a physical location. The equipment location is used to find the equipment for maintenance. Also, the location is useful to break up the maintenance schedules by department.

Maintenance history: A record should be kept of all maintenance performed on equipment, including scheduled maintenance, repairs, software upgrades, and incident investigations. Dates of service should be included in this history.

Work coding: For benchmarking and trending, the type of maintenance being performed on the equipment is required. The University of Vermont uses a work order coding system where a work order is generated for each maintenance event and a work order type is assigned to each work order. A sample of work order types are listed in the table on page 12.

Work order coding is important in measuring the success of the maintenance program and for identifying areas that need to be addressed. For example, if there are a lot of work orders indicating use error for a device, the trend may indicate the clinical staff needs to be trained in the proper use of the equipment. Below is an example of the use of trending data to identify equipment with a high percentage of use error. As a benchmark, equipment with a use error per device of greater than 10 % needs to be addressed. In this example, hypo/hyperthermia units have a use error percentage of around 12 %. Further investigation will need to be done as to why the failures occur.

Work order types for corrective maintenance

Work Order Type	Definition
08-REPR-MAINT	Device failure could have been prevented with maintenance, such as replacing tubing
09-REPR-RAND	Device failure could not be prevented
10-REPR-USR ERR	Device failure was caused by improper clinical use
11-REPR-DAMAGED	Device failure was caused by abuse
12-REPR-NO PROB	Reported failure could not be reproduced
14-RE-REPAIR	Device failed for the same problem within 30 days of being repaired previously
18-TR-RAND B	A minor problem found during the scheduled performance testing
19-TR-RAND C	A major problem found during the scheduled performance testing
23-TR MAINT B	A minor problem found during the scheduled performance inspection that could have been prevented with maintenance
24-TR-MAINT C	A major problem found during the scheduled performance inspection that could have been prevented with maintenance
60-PLANNED	Planned maintenance
57-NOT TESTED	Device not tested during the regularly scheduled performance inspection
58-FT AFTER 57	Device that missed its regularly scheduled inspection has received a performance inspection
63-TR B – NFR	A minor problem found during the scheduled performance testing that does not require follow up
64-TR C – NFR	A major problem found during the scheduled performance testing that does not require follow up
65-TR A – NFR	Scheduled maintenance (e.g. battery replacement) was not performed, no additional follow up is necessary
Other work order types	
15-INCOMING P	Device passes initial performance inspection performed before the device is put into service
16-INCOMING F	Device does not pass initial performance inspection
25-FT ADD P	Device passes initial performance inspection performed after the device is already in service
26-FT ADD F	Device does not pass initial performance inspection and has already been in service
27-FT NO ADD P	Device passes initial performance inspection but will not be added to the inventory
28-FT NO ADD F	Device that will not be added to the inventory does not pass initial performance inspection
30-PROD ALERT	A recall or alert has been issued for a device
33-RECALL MOD	Work done in answer to a recall, such as a software upgrade or parts replacement
37-INCIDENT INV	Investigation of an incident involving the device
44-CALIBRATION	Device requires calibration
59-INV DELETE	Device is taken off of the inventory

Deciding which devices to put on the inventory

The process to determine what devices will be managed as part of the equipment management system is crucial to the success of the system. All devices must be evaluated to determine if they should be managed.

The University of Vermont uses three major classifications of devices: clinical, utilities, and general. Within the clinical classification, two subgroups will be identified: life support and non-life-support. Other equipment may be inventoried and tracked for financial or other reasons but is not included in this process.

Clinical equipment is any equipment used for treatment, monitoring, or diagnosis of patients. Life support equipment is clinical equipment that takes over a function of the body and will cause immediate, within minutes, death if removed. Under this definition a ventilator will be considered life support equipment, whereas a hemodialysis machine is not considered life support. Even though the hemodialysis machine takes over the function of the kidney, removal of the patient from hemodialysis will not cause immediate death.

All major device classes should be assessed for inclusion based on function, risk, maintenance requirements, historical incidents, and regulations and each device type should be evaluated. Evaluations should be performed on new device types as they arrive at the hospital. All equipment used in the hospital should be evaluated regardless of ownership. Most commonly, devices will fall into the clinical classification. A maintenance schedule should be determined for these devices based on the risk criteria discussed in Chapter 3.

Device inclusion must be performed and documented prior to any equipment use preferably during the technology planning stage prior to arrival at the facility. This process should be utilized for owned, rented, loaned, demonstration or leased equipment.

The factors must include function, risk, maintenance requirements, and history of incidents. The University of Vermont has developed a Device Inclusion Worksheet to facilitate this process.

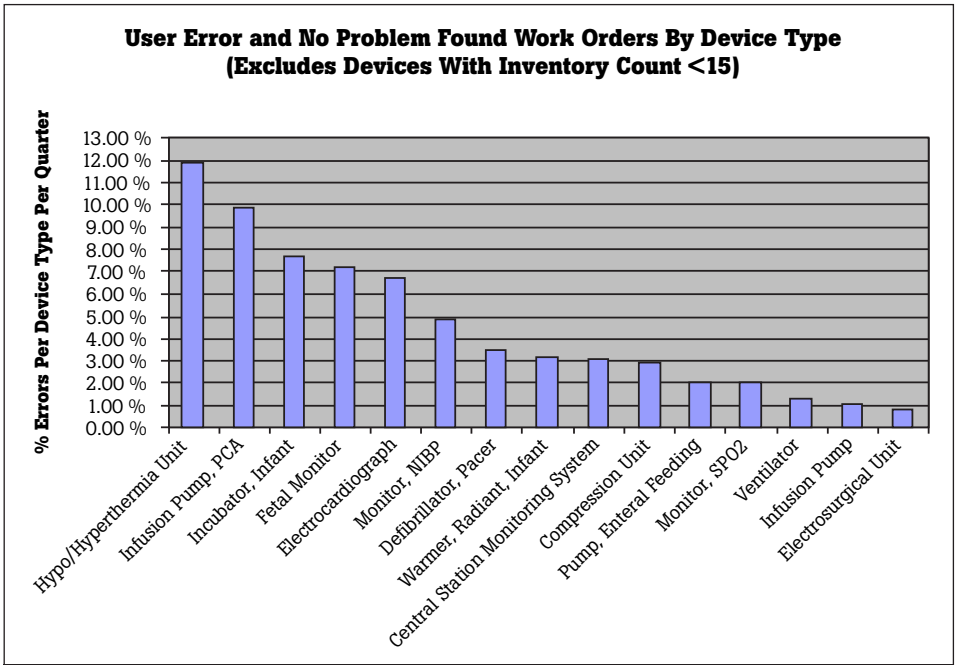


Figure 2.

Device inclusion worksheet

Device information

Device type		Owner	Hosp	Vendor	MD	Other
Manufacturer		Department				
Model		Tester	Hosp	TSP	Mfr	User
Serial number		Prev maint	Hosp	TSP	Mfr	User
Control number		Tests/year	1x	2x	3x	4x

Inclusion assessment

The intent is to capture all powered devices that by function, physical risk, maintenance requirements, or a history of incidents or safety problems should be managed as a part of the medical equipment management system. Some devices have a borderline inclusion between medical equipment and utilities, so tests for inclusion in the utilities management program are included.

1: Life support equipment		
Would failure of this device result in immediate death of the patient? And	Yes	No
Is the powered device used for direct patient treatment or care?	Yes	No
An answer of "**Yes**" to both of the above questions indicates that the device should be managed in the medical equipment inventory as a **life support device**.		
2: Medical equipment		
Is the powered device used for direct patient treatment or care?	Yes	No
Does the powered device provide diagnostic/monitoring information used in treatment?	Yes	No
Does this powered device come in contact with the patient?	Yes	No
An answer of "**Yes**" to any of the above three questions indicates that the device should be included in the medical equipment management program and be inventoried under those provisions.		
3: Utilities equipment		
Does this device facilitate life support functions?	Yes	No
Does this device support infection control systems?	Yes	No
Does this device support facility environmental systems?	Yes	No
Does this device support critical facility utility systems?	Yes	No
Does this device support essential communications systems?	Yes	No
If the device fails to meet the medical equipment requirements, but there are any "Yes" answers to the utilities equipment questions, the device should be included in the utilities equipment management program.		
4: Clinical and physical risk		
Does the device pose risk to the patient or staff when used in the facility?	Yes	No
Would failure or loss of use of the device adversely affect the deliver of health care?	Yes	No
Does this product or class of device have a history of incidents or safety recalls?	Yes	No
5: Maintenance requirements		
Does the device require periodic inspection in order to ensure safe delivery of care?	Yes	No
Does the device require periodic performance testing to ensure safe delivery of care?	Yes	No
Does the device require periodic preventive care to ensure safe delivery of care?	Yes	No
If the device fails to meet the requirements for Medical or Utilities Equipment, but there are "YES" answers to the above questions in Clinical and Physical risk or Maintenance Requirements, the device should be managed on a general equipment inventory with preventive maintenance or testing as appropriate.		
Management program assignment		
This device will be assigned as Life Support Equipment	Yes	No
This device will be assigned as Medical Equipment	Yes	No
This device will be assigned as Utilities Equipment	Yes	No
This device will be assigned as General Equipment	Yes	No
This device will be NOT be included in any equipment management program	Yes	No

Completed by: _____ **Date:** _____

Incoming inspections

The initial test for a new piece of equipment prior to the use in patient care is called the Incoming Inspection. This inspection serves to ensure the equipment passes all performance and safety requirements prior to use. This is typically the most rigorous test performed of all inspections. A test form should be used to document test results. Incoming inspections should be done on all medical equipment, regardless of whether owned, rented, leased, loaned, or on demonstration equipment.

Each device should be evaluated per the Device Inclusion Worksheet to determine the inventory classification. All medical equipment determined to be on a management program needs to receive a performance and safety test prior to patient use. Working with clinical staff is required to ensure all medical equipment receives an incoming inspection, including demo equipment brought in by vendors.

If the equipment passes the inspection, the device should be entered into the hospital's inventory. Inspection labels, warranty labels, and battery labels are also placed on the device when appropriate. The equipment can now be placed into service.

If the device does not pass the inspection, it is not placed into service and the deficiencies are noted. Many devices receiving an incoming inspection are covered under warranty. In this case, the vendor should be contacted to either exchange or repair the equipment. The equipment should not be placed into service until it can successfully pass the incoming inspection.

Incoming inspection of temporary medical equipment

Temporary medical equipment is equipment that is not owned by the hospital, and which is either used for patient care on a sporadic basis, or which will be used for a limited amount of time at the facility, typically 90 days or less. Such equipment may include rental equipment, a sales demo, or patient owned equipment. Temporary medical equipment needs to be properly maintained just as hospital owned equipment does to protect the safety of the patient.

All medical equipment needs to undergo an incoming inspection. Medical equipment that will be at the facility for a single time of 90 days or less does not need to be added to the equipment inventory, although a record should be kept of the initial incoming inspection. Equipment that will be at the facility for longer than 90 days should be added to the equipment inventory to be tracked just like hospital-owned equipment.

Equipment that will be brought repeatedly to the facility, such as a rental device, will need to have an incoming inspection and be added to the inventory. Additionally, the vendor should be required to certify that each time the device is brought to the facility, the equipment has been maintained, and that the device is safe and ready for use. The University of Vermont uses the following Vendor Safety Certification Form to ensure these devices are safe and ready for use when they are brought into the facility.

Vendor Safety Certification Form
Medical equipment often is provided to facilities for use as loaners, demonstration, rental or lease. It is sometimes not possible for the hospital or its biomedical equipment agent to adequately test these devices before they are used clinically. As a prerequisite to patient use of devices that cannot be fully tested by the hospital, the hospital requires the vendor to provide a certification that the device(s) is/are safe for use at the facility for a specific period of time or under specific circumstances of use.

Clinical Use Prohibited Without This Certification

Hospital:_____

Department:_____

Manager: _____ Date: _____

Device Description: _____

Vendor:_____ Contact: _____

Serial Numbers of All Devices:_____

Intended Use of the Device: _____

Dates of Use: Start:_____ Stop: _____

Vendor completes this part:

_____ This vendor certifies this device is provided to the facility in safe and useable condition, and is FDA approved for the intended clinical procedure(s). This vendor has or will test the device for proper function prior to clinical use, but after arrival at the facility. Training will be provided to staff on safe use and potential risks.

_____ This device is an investigational device for which FDA approval does not exist as of yet. The device will not be used clinically until all hospital investigational review board approval is received. Training will be provided on safe use and potential risks.

_____ This equipment is provided repeatedly to the hospital and is maintained by the vendor. It is checked between assignments to different facilities, and records of maintenance are provided annually to the facility. Ongoing performance and safety testing is provided, and the vendor certifies that the device is safe for use as provided at delivery.

_____ Non-hospital employees who will be delivering and/or operating the equipment are appropriately trained and qualified to be transporting, setting up, and operating the equipment.

Note any special conditions: _____

_____

Vendor Signature: _____ **Date:** _____

Facility Signature: _____ **Date:** _____

Documentation

Documentation is very important to any maintenance program. Tracking what maintenance has been performed is impossible if there is no documentation. All maintenance, scheduled and unscheduled, should be recorded in the equipment history.

The University of Vermont uses documentation by exception to report the results of scheduled performance inspections. Documentation by exception is the process of documenting failures only. A work order is completed only for those devices that fail to meet a routine, scheduled inspection against safety, performance or quality assurance criteria. Devices that pass the scheduled inspection criteria are rendered acceptable and do not require written test forms or additional work orders.

All incoming inspections, other additions to inventory, and devices that have undergone corrective maintenance should have a documented PM/inspection form and work order completed.

Locating missing equipment

As stated above, the University of Vermont uses a system of documentation by exception. A work order needs to be opened for each problem noted during the scheduled test round. The work order coding system contains specific work order types for problems encountered during scheduled maintenance.

One work order type 'Not Tested' is particularly useful. This work order type is used to mark equipment that did not receive its scheduled inspection. Equipment may miss its scheduled inspection for a variety of reasons, most commonly because the equipment could not be physically located. The equipment may also miss an inspection if it is being used on a patient and cannot be removed or if the equipment has been sent out for repair.

Every effort should be made to locate and inspect equipment marked as 'Not Tested' and working with clinical staff to locate this equipment will be required. A list of missing equipment should be sent to the department so that the staff can keep watch for the missing equipment. A protocol should be established for clinical staff when they find the equipment. If possible, the equipment should be set aside for testing. Designating a storage area for this purpose is desired.

At the University of Vermont, a work order is created for devices that were not tested during their scheduled test round. The work order is left open for up to thirty days while biomedical equipment technicians attempt to locate the equipment. During this time, nursing staff is asked to assist in locating the equipment. A notice is sent to the department manager with a list of equipment that needs to be located for inspection. If nursing staff locates the missing equipment, the equipment is set aside, if possible, until it can be inspected and biomedical personnel are notified.

Once the equipment has been inspected, another work order is created to show that the equipment received its scheduled maintenance. This work order has a type that indicates a functional test following a 'Not Tested' work order. Again, the coding system is important, as it allows these types of maintenance events to be identified.

Labels

Labels are an easy and effective way to communicate information about medical equipment. The University of Vermont uses a variety of labels to indicate specific data necessary for technology management, regulatory requirements, and for safety. Labels may be used for performance inspections—bi-annual, annual, semiannual and general, battery installation, specific calibration, warranty, hazards and warnings, and upgrade or recall data. In addition, a unique identifier control number is placed on each piece of equipment for ease of device tracking. The following are examples of these labels:

Control number tags are made of aluminum and attached with a permanent adhesive. These tags need to be rugged in order to stand up to repeated cleaning and disinfecting of the equipment. Other labels are made of a material that allows them to be peeled off and replaced. Labels that require written information should be filled in using permanent marker, to avoid fading of the ink.

Inspection labels that include a next inspection due date are especially useful. Clinical staff should be trained that if they find a piece of equipment with an outdated inspection sticker, they should put the equipment aside if possible and contact biomedical personnel.

Care should be taken to ensure labels are not placed over important information, such as warnings, contraindications, and instructions.

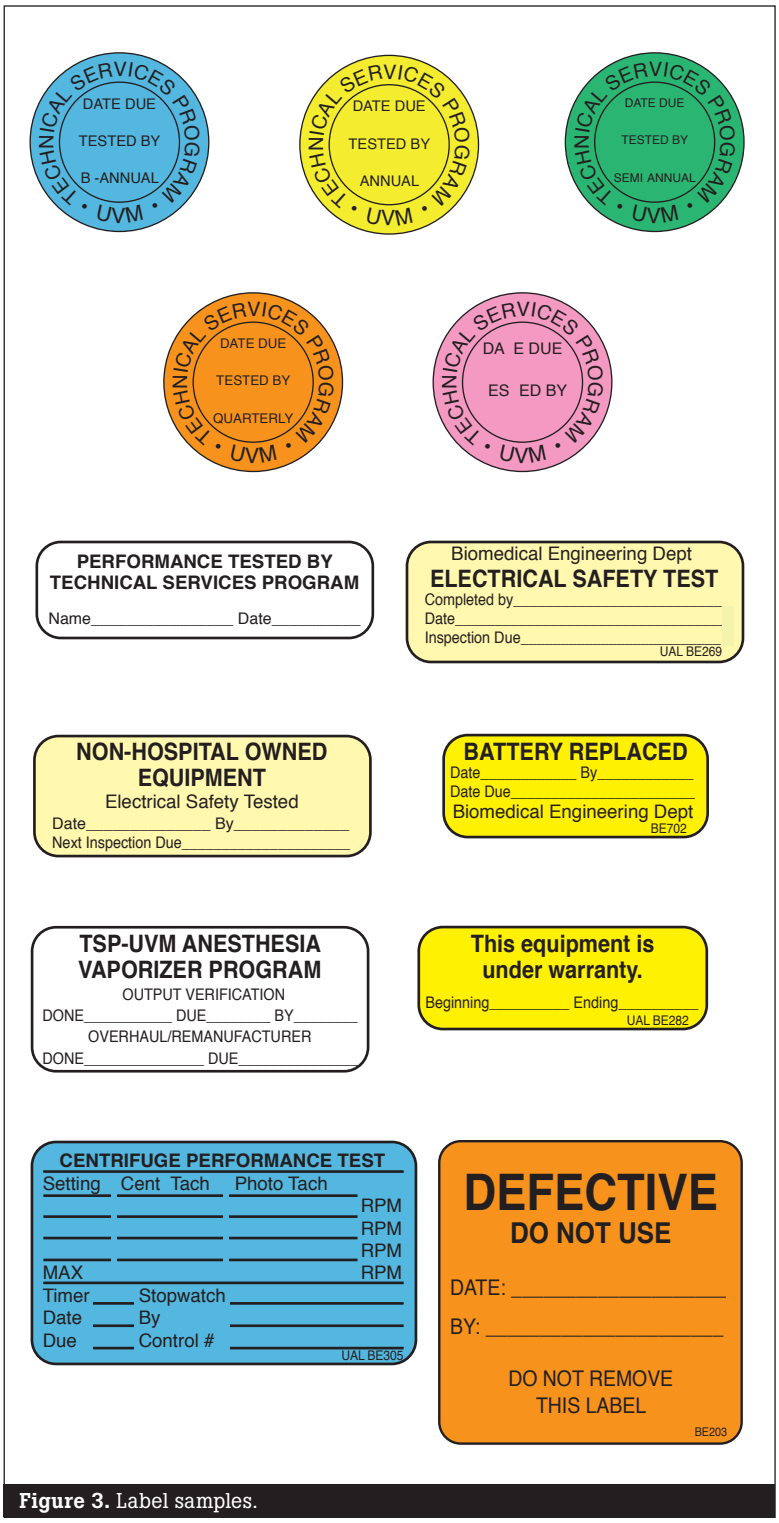


Figure 3. Label samples.

Forms

Testing checklists should be developed for each device type. These lists are useful because they outline recommended maintenance procedures and provide numerical criteria for quantitative tests.

The maintenance checklists should be filled out during an incoming inspection or testing following a repair. The University of Vermont uses documentation by exception policy and does not fill out a maintenance checklist for the successful completion of a scheduled performance inspection. Maintenance forms can be either paper or electronic format. Placing maintenance checklists on a handheld device such as a PDA that can be filled out electronically may be useful.

The maintenance forms should contain information on what equipment is being inspected, the date the inspection occurs, and who is to perform the inspection. A list of maintenance tasks should be broken down by subsystem and numerical criteria given for quantitative tests. For example, the measured flow rate of an infusion pump should be within 10 % of the set rate. This criterion appears on the test form next to the task for flow rate accuracy.

The checklist has an option for each maintenance task as either passed, failed, or not applicable. Devices that have maintenance tasks that fail should not be put back into service until the problem has been corrected.

The not-applicable category is necessary as the maintenance checklists are generic by device type and, since device operation varies from model to model, not every maintenance task can be performed on every device. For example, the centrifuge maintenance checklist includes timer accuracy, operation of the brake, and alarm activation. High-end centrifuges will have all of these functions. However, simpler centrifuges may not have these functions to be tested. This doesn't mean the device is unsafe to use, it simply means the equipment does not have those functions.

Every maintenance task that needs to be performed on every device can be included on the maintenance checklist. Device function and operation vary greatly by model and manufacturer. Reference to the equipment's service manual for any additional maintenance tasks is required. A sample form for Infusion Pumps is shown on page 20.

Infusion pump procedure

Estimated time: 45 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer
IDA4 Plus Infusion Device Analyzer
Tubing set for infusion pump
Reservoir to connect to tubing set (bag or bottle)
20 cc or larger syringe
3 way stopcock
Tubing and connectors to connect to IDA 4 Plus

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Clean flow detector	
			Replace battery every 24 months	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify unit operates on battery	
			Pole clamp function	
			Flow rate accuracy	± 10 %
			Volume accuracy	± 10 %
			Infusion complete/KVO	
			Occlusion detection pressure	± 1 psi
			Piggyback infusion	
			Alarm function	
			Complete model-specific performance testing	

 ©University of Vermont, Rev. 2 – Confidential

Safety

Maintaining and inspecting medical equipment involves a number of risks, including electrical and mechanical hazards. Many maintenance tasks include precautions to minimize theses risks. Always follow manufacturer's guidelines for safety precautions during specific tests. Being aware of potential hazards will allow risks to be minimized.

Electrical hazards: Electricity poses a significant hazard for biomedical personnel. Not only are you exposed to electrical hazards during a repair, but also while testing medical equipment for electrical safety. Electrical safety testing requires the simulation of faults and extra caution should be taken.

Electrical safety testing should be done before performance testing. The continuity between the chassis and the ground pin on the plug should be confirmed first; this is the primary protection against electrical shock to equipment users. Check the power cord for frayed installation or exposed wires. Damaged power cords should be replaced immediately.

Testing should never be performed on equipment that is in use on a patient. As stated above, electrical safety testing simulates electrical faults and can expose the patient to dangerous voltages and currents. Work with clinical staff is necessary to either disconnect the equipment from the patient or to arrange a time to test the equipment when it is not in use. The electrical safety analyzer should be plugged into a properly grounded outlet to prevent a shock hazard while testing a piece of defective equipment.

Line voltage is used during lead isolation testing. This test should only be performed with test equipment that has been designed for safe application of the voltage to the patient leads. Do not touch the leads during lead isolation testing, as this may cause a shock.

In order to service equipment, removing the cover is necessary. This will expose more electrical hazards. Jewelry, such as rings and watches, should be removed to avoid accidental contact with electrical components. Power should be removed from the equipment during the repair process whenever possible. As many tests as possible should be performed without power to the equipment, for example, using an ohmmeter to check semiconductors for a short circuit. If you must test a live circuit, be careful not to accidentally cause a short with your test leads, as this can cause damage to components. Also be aware that capacitors can store a charge even after the equipment has been unplugged for some time.

If a circuit board needs to be moved from their mountings, insulating material should be placed between the board and anything that may cause a short. Adjustments to potentiometers should be made with insulated tools.

Use caution while handling static sensitive components, as even small amounts of static electricity can cause damage to the components. Use an anti-static wrist strap to avoid damage to sensitive components.

Mechanical hazards: Mechanical and pneumatic assemblies pose hazards as well and should be given appropriate caution. Moving parts can cause injuries such as cuts and crushed fingers. Unsecured fittings on pneumatic systems can blow off under pressure and become projectiles. Compressed gases also pose fire, as well as suffocation hazards.

When inspecting equipment with moving parts, for example, irrigation units and electric beds, fingers, and clothing should be kept away from the moving parts. Maintenance such as visually inspecting for wear, cleaning, and lubrication should be done with the equipment powered off, and unplugged if possible. Jewelry should be removed to avoid getting caught on moving parts and loose clothing, such as ties, should be secured.

Compressed gas cylinders pose unique hazards and should be handled carefully. Oxidizing gases such as oxygen and nitrous oxide pose a serious fire hazard. Additionally, gases such as nitrogen, nitrous oxide, and carbon dioxide are a suffocation hazard in large amounts.

Damage to the cylinder valve can have catastrophic effects. The cylinder will rapidly discharge its contents, possibly causing a suffocation or fire hazard and as the cylinder discharges, will become a projectile. Care should be taken to never drop a gas cylinder. If a cylinder for a piece of equipment is removed, the cylinder should be laid down on the floor. A cylinder standing on end is easily knocked over. Do not drag, roll, or slide cylinders, as this can damage the valve.

Combustible substances such as oil and grease should not be used with compressed gas. Likewise, you should not handle cylinders, hoses, regulators, or other gas system components with oily hands or gloves. Oxidizing gases such as oxygen and nitrous oxide will ignite violently when combined with a heat source, such as an electrical spark or even frictional heat caused by gas moving through narrow hoses, and a combustible fuel.

Make sure connections to high pressure systems are secure. High pressure gas can cause connectors to become projectiles. To avoid connectors from suddenly disconnecting, use threaded or positive locking connectors. Do not use friction fittings, as they will not stand up to a high pressure.

Infection control: Another risk inherent to maintaining medical equipment is biological hazards. Infection control guidelines need to be followed in order to prevent both contracting diseases and to avoid the spread of nosocomial infections. The easiest and most effective method to prevent the spread of infection is with proper hand washing. Hand washing should be performed before eating, after handling soiled equipment, after removal of gloves, after the end of a shift before you leave the facility, and any time hands are obviously soiled.

Food and drinks should be kept away from benches, shelves, and other areas where potentially contaminated medical equipment is being serviced or stored. Applying cosmetics and handling contact lenses should also be avoided in these areas.

Equipment should only be inspected or repaired after it has been disinfected. Clinical staff should be educated on the proper way to disinfect equipment and what type of disinfectant to use. Certain disinfectants can cause damage to equipment such as breaking down the plastics used for the outer case and causing the case to become brittle. Check with the equipment's user manual or the manufacturer for instructions on how to disinfect equipment and what disinfectants can be used safely.

If work must be done on equipment that has not been cleaned, wear personal protective equipment such as gloves, mask, and gown. Disinfect the work area when done and wash hands thoroughly after removing the protective equipment.

The Blood borne Pathogen Standard became a federal regulation in the United States enforced by the Occupational Health and Safety Administration (OSHA) on March 6, 1992. The purpose of the regulation is to limit occupational exposure to blood and other potentially infectious materials. The focus of the mandate is to utilize universal precautions and work practice controls to reduce the exposure risk to HIV, hepatitis and other infectious diseases. Biomedical equipment technicians are specifically mentioned as an at-risk group due to their work on medical equipment that may be contaminated. The regulation states: **"Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping, and shall be decontaminated as necessary"** (Paragraph (d)(2)(xiv). The only exception in the standard is if decontamination of the equipment is not feasible. In this case, a biohazard label, and a description of the contamination must be placed on the device.

At the University of Vermont, all staff with occupational exposure to blood borne pathogens, BBP, receive initial training before exposure to the BBP environment and annual refresher training. The hepatitis B vaccine is provided to staff upon completion of the initial BBP training. Universal precautions, a method of infection control in which all blood and body fluids are treated as if known to be infectious for HIV, HBV and other blood borne pathogens, and engineering/work practice controls are used to limit occupational exposure to blood and other potentially infectious materials.

Tuberculosis is a serious bacterial infection that can spread from individual to individual through the air and may scar lungs, kidneys, bones, or the brain. Tuberculosis is highly contagious and can be fatal, though it is usually curable with medication.

At the University of Vermont, every staff member who performs work in a healthcare is tested using the PPD Mantoux skin test prior to work in the environment, with clinical follow up is required for a positive test result. Staff are tested annually thereafter for the presence of the TB virus.

Storage

Equipment that is not used every day is often put into a storage room. Equipment should be cleaned before being put into storage. Equipment that has a battery should be stored plugged in to keep a charge on the battery.

Equipment in active storage will need to have scheduled maintenance like other equipment, even if it has not been used since the last performance inspection. Regularly scheduled performance inspections Ensure the equipment is safe and ready for use.

Cleaning equipment

Medical equipment needs to be cleaned to prevent the spread of inspections and also to keep the equipment in operational condition. For example, residue from adhesive tape can make displays difficult to read. The manufacturer's cleaning procedures in the equipment's operation manual should always be followed to prevent damage caused by cleaning.

Some cleaners may damage equipment. The University of Vermont has found problems associated with cleaning solutions, including cracked and brittle cases on equipment and degradation of panel membranes. In this case, work order trending revealed a high percentage of 'damaged' work orders for infusion pumps. Upon further investigation, it was found that the cleaning solution that was being used to disinfect the pumps between patients was causing the plastic cases to turn brittle and crack. Working with the manufacturer of the pumps, a recommendation for a suitable disinfectant was made.

Always check the equipment operation manual in the proper way to disinfect the equipment. The manual should list the preferred cleaning method and what cleaners can be used. Also be aware that cleaners can sometimes discolor, etch, or soften materials such as plastics often used in equipment cases. Always test cleaners in an inconspicuous area before using.

CHAPTER 5: Electrical safety

Electrical safety is an area of concern related to medical devices. Electrical shock can cause disruptions during healthcare procedures, injury, and death. Physiological effects range from a tingling sensation to serious burns and electrocution. Excitable human tissue is very sensitive to current in the frequency range of electrical power systems worldwide—50–50 Hertz. Figure 4 shows the effects of current flowing from one skin contact point to another. Macroshock is the term applied when electrical current is applied externally.

The electrical safety issue takes on added significance related to electrically-susceptible patients. For cardiac procedures, electrically conductive catheters may be placed into the heart while the patient is connected to medical equipment. The skin is a high electrical resistance, but internal body components such as blood and muscle are a low electrical resistance. Currents as low as 20 microamps can cause ventricular fibrillation in experiments conducted with dogs when a conductor made direct contact to the heart. Microshock is the term used to describe direct shocks to the cardiac muscle.

From the data for macroshock and microshock, limits have been established for leakage current. These limits are contained in various standards worldwide. In the case of equipment designed for low resistance, direct contact with patients including indwelling catheters, electrical isolation design techniques are applied to reduce the current flowing to the patient to microamperes even at line voltage levels. Even under device failure or short circuit conditions, the patient is protected from microshock. These techniques may utilize isolation transformers and optical circuits. Thus, electrical safety standards specify low microampere limits for direct patient contact equipment.

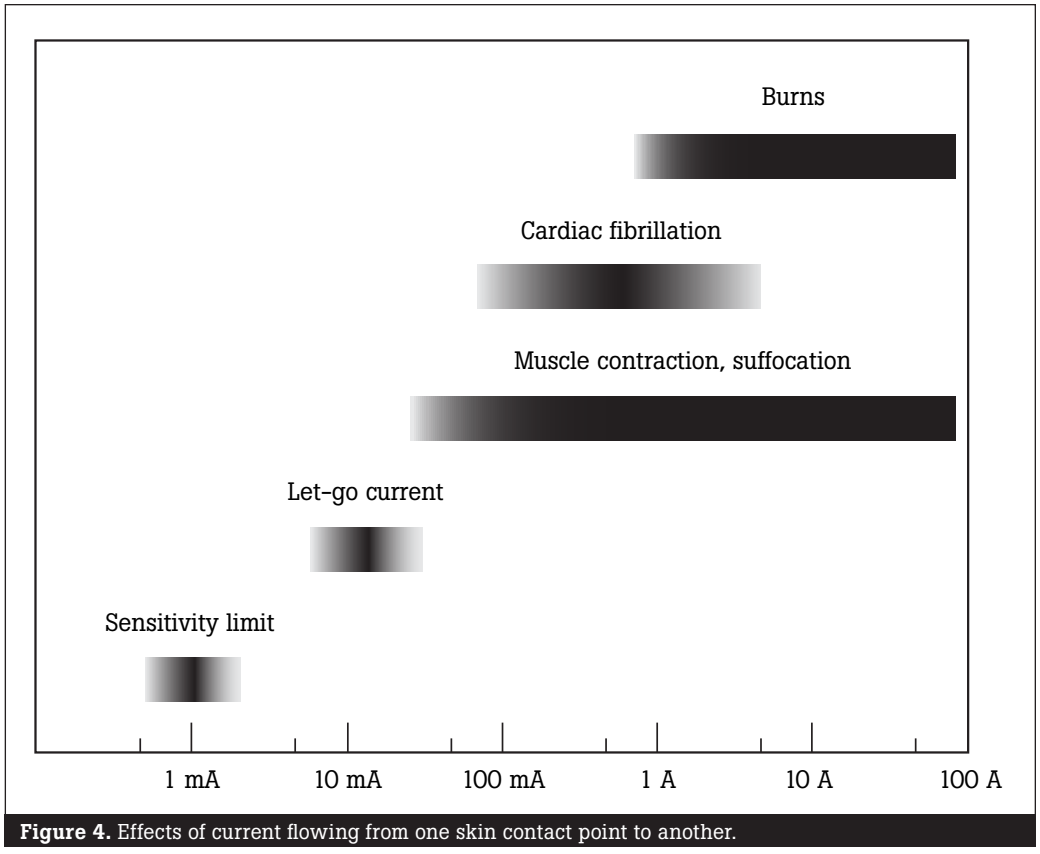


Figure 4. Effects of current flowing from one skin contact point to another.

 ©University of Vermont, Rev. 2 – Confidential

To reduce leakage current to negligible levels, chassis grounding is utilized to shunt any leakage or fault current to ground—not to the patient or staff. Figure 5 shows pictorially and schematically the hazard current from the electrical failure being safety shunted to ground through this alternative pathway. Effective grounding can only be achieved with very low resistance pathways to ground on the order of tenths of an ohm. Grounding is another measurement specified in electrical safety standards for medical devices.

The basic electrical safety tests are:

1. Visual inspection of cables, plugs and connectors
2. Measurement of ground wire resistance
3. Measurement of chassis and patient lead/contact isolation

Other tests may be required depending upon the country, state/province/department, or local codes.

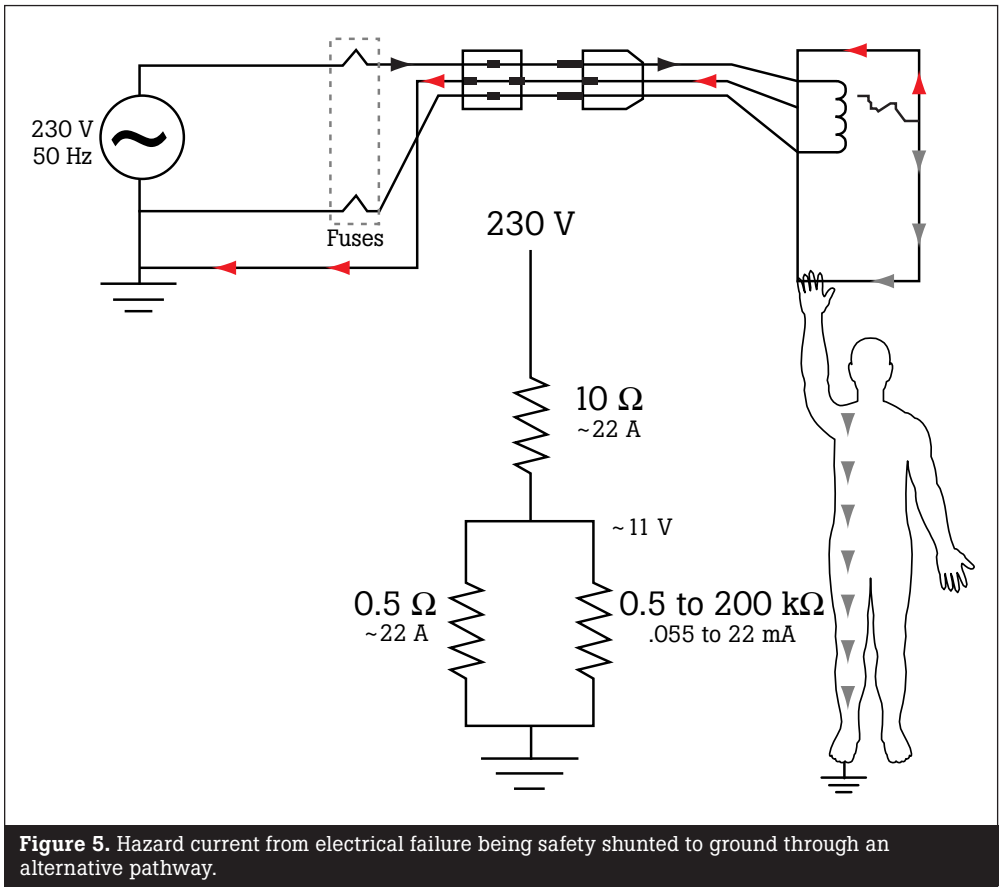


Figure 5. Hazard current from electrical failure being safety shunted to ground through an alternative pathway.

Electrical safety standards

Electrical safety standards have been developed in the United States, European countries, and other parts of the world. The standards differ in criteria, measurements, and protocol.

The International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) based in Europe are organizations that provide standards worldwide in partnership with the World Trade Organization. These standards include those for electromedical equipment. There are general and specific standards for medical device electrical safety.

The primary standard for medical devices has been IEC 60601. General requirements for protection against electric shock hazards are covered in IEC 60601.1, Section 3.

In this standard, each instrument has a class.

- **Class I** – Live part covered by basic insulation and protective earth
- **Class II** – Live part covered by double or reinforced insulation
- **Class IP** – Internal power supply

Each patient applied part or patient lead has a type.

- **Type B** – Patient applied part earthed
- **Type BF** – Patient applied part floating (surface conductor)
- **Type CF** – Patient applied part floating for use in direct contact with the heart

The terminology used in IEC 60601.1 includes

- Protective earth resistance
- Earth leakage current
- Enclosure leakage current
- Patient leakage current
- Patient auxiliary current
- Mains on applied part (MAP)

To represent the impedance of a patient, the test load in Figure 6 has been developed. Leakage current measuring devices use this impedance circuit for measurements.

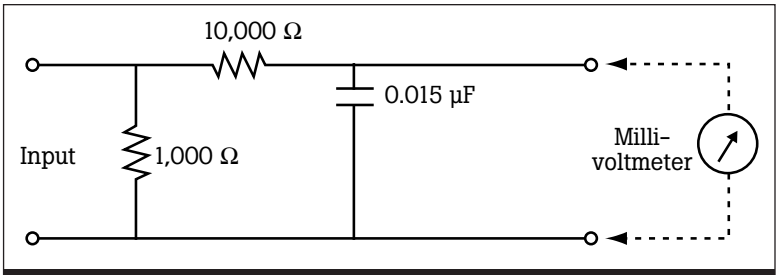


Figure 6. Impedance of a patient test load.

Leakage measurements (IEC 60601.1, Section 3, Clause 19 limits have been developed for equipment types and measurements. NC is normal conditions and SFC is single fault conditions. Some of the measurements are only applicable to manufacturer design testing.

 ©University of Vermont, Rev. 2 – Confidential

Leakage current (µA)		Earth leakage current mA	Enclosure leakage current (µA)	Patient leakage current AC (µA)	Patient leakage current DC (µA)	Patient leakage current mains on applied (µA)	Patient auxiliary current (µA)	Patient auxiliary current DC (µA)	Patient auxiliary current AC (µA)
Type B	NC	5	100	100	10	—	100	10	100
	SFC	10	500	500	50	—	500	50	500
Type BF	NC	5	100	100	10	—	100	10	100
	SFC	10	500	500	50	5000	500	50	500
Type CF	NC	5	100	10	10	—	10	10	10
	SFC	10	500	50	50	50	50	50	50

Other important points about IEC 60601.1 are the use of up to 25 amperes AC for protective earth testing, leakage current is measured at 110 % of mains voltage, and performance of dielectric strength/insulation testing.

A new IEC standard is used for medical device testing in hospitals. IEC standards 62353 applies to testing of medical equipment and medical electrical systems, which comply with IEC 60601-1. IEC 62353 was developed because IEC 60601.1 is a type-testing standard with no risk management criteria and is impractical for testing in the hospital environment.

IEC 62353 tests include those prior to use on patients, during schedule periodic testing, and after repair. Thus, this standard is for hospitals and does not address equipment design. In Annex E of the document, the manufacturer is requested to provide information on testing interval and procedure based on risk, typical usage, and device history. Minimum interval requirements for life support and other critical equipment is set at 24 months.

In the United States, there are several primary and secondary organizations setting standards:

1. **National Fire Protection Association (NFPA) –** NFPA 99, Standard for Healthcare Facilities is the primary standard addressing electrical safety testing affecting healthcare institutions. Other publications are NFPA 70, National Electrical Code, and NFPA 70E, Electrical Safety in the Workplace.
2. **Association for the Advancement of Medical Instrumentation (AAMI) –** ANSI/AAMI ES1, Safe Current Limits for Electromedical Apparatus is another commonly accepted standard.
3. **Underwriters Laboratories (UL) –** UL544, Medical Equipment requirements is a standard for manufacturers, not hospitals.

These standards may be referenced by accreditation, code or regulatory organizations such as the Joint Commission, Occupational Health and Safety Administration or other organizations monitoring healthcare institutions in the United States. The Appendices describe the above standards and test setups.

Global harmonization of standards has lead to the development of world wide standards. After the deadlines below, equipment must be certified to the IEC60601-1 standard or the device cannot be sold in that country.

- USA uses UL2601-1
  — The deadline was December 31, 2004
- Europe uses EN60601-1
  — The deadline was June 13, 1998
- Canada uses CAN/CSA-C22.2 No. 601.1-M90
  — The deadline was January 1, 2000

Electrical safety testing

Testing requirements and sequence according to IEC 62353 Annex C are shown below. Only measurement equipment that meets IEC 61010–1 should be used.

The sequence outlined in Figure 7 should be followed. For example, protective earth resistance should be measured prior to leakage current measurements.

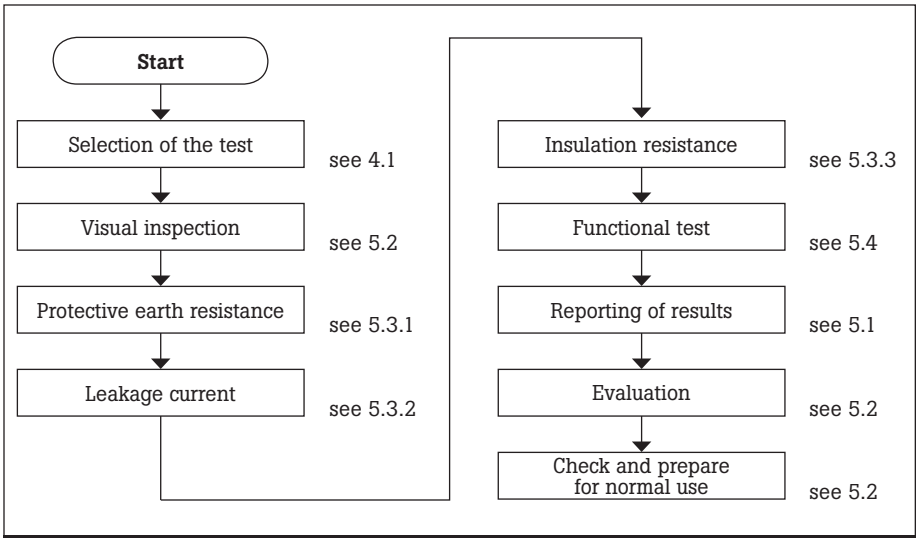


Figure 7. Testing requirements and sequence according to IEC 62353 Annex C.

General connections to an electrical safety analyzer (ESA) are shown in Figure 8. Consult the operational manual for specifics for your ESA.

Documentation requirements for IEC 62353 include:

- Identification of the testing group (hospital department, independent service organization, manufacturer)
- Names of the persons, who performed the testing and evaluation(s)
- Identification of the equipment/system (e.g. type, serial number, inventory number) and the accessories tested
- Tests and measurements
- Date, type, and outcome/results of
  - Visual inspections
  - Measurements (measured values, measuring method, measuring equipment)
  - Functional testing according to 5.4
- Concluding evaluation
- Date and signature of the individual who performed the evaluation

Computerized record-keeping systems are greatly preferred for data storage, search, review, and analysis. Note the device fields must be standardized.

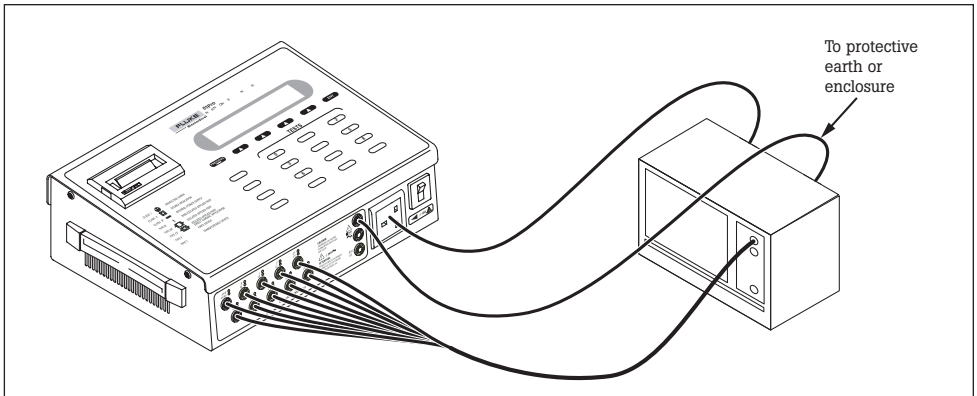


Figure 8. General connections to an electrical safety analyzer.

 ©University of Vermont, Rev. 2 – Confidential

FLUKE®
Biomedical

Electrical safety procedure

Estimated time: 5 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: Fluke Biomedical ESA620 or equivalent

Test Result						
Pass	Fail	N/A				
Physical condition						
			Device is clean and decontaminated			
			No physical damage to case, display, mounts, cart, or components			
			Switches and controls operable and correctly aligned			
			Display intensity adequate for daytime use			
			Control numbers, labeling, and warnings present and legible			
			Fuse rating is appropriate			
			Power cord, accessory cables, charger, patient cables, connectors			
			Integrity of mechanical parts			
Electrical safety				**Criteria IEC 62353**		
			Ground wire resistance	0.3 Ω		
			Current in µA	**Applied part**		
				Type B	**Type BF**	**Type CF**
			Equipment leakage – alternative method			
			For accessible conductive parts of Class I equipment connected or not connected to the protective earth conductor	1000	1000	1000
			For Class II ME equipment	500	500	500
			Equipment leakage – direct or different method			
			Equipment leakage current for accessible conductive parts of Class I ME equipment connected or not connected to the protective earth conductor	500	500	500
			Equipment Leakage current for Class II ME equipment (NC)	100	100	100
			Applied part leakage current – alternative method (a.c.)			
			Applied part leakage current of applied part	–	< 5000	< 50
			Applied part leakage current – direct method (a.c.)			
			Total patient leakage current mains voltage on applied part	–	5000	100
			Insulation test (optional) 500 V dc applied	< 2 MΩ		

Tested by: _____ Date: _____

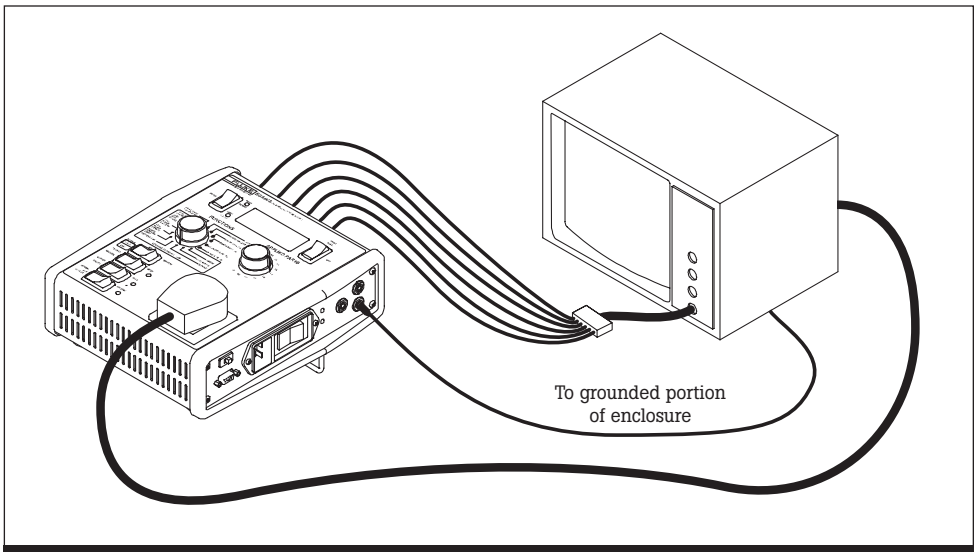


Figure 9. ESA601 connected to a device under test.

Physical condition

Verify the case integrity and look for damage. Ensure the device is not contaminated. Check the controls, indicators, and displays. Verify the labeling is appropriate, not damaged and legible. Check the fuse has the proper rating. Visually inspect the power cord, plug, any cables, connectors, chargers, or other external connections. Verify any mechanical parts are in good condition.

Electrical safety analyzer (ESA) setup

Place controls in startup mode (e.g. ESA 620 function switch to OFF). Insert measurement cables into the ESA. Plug the ESA into the power receptacle and turn on. Ensure the line voltage is appropriate as read from the ESA.

Note: All tests below should be performed with the device OFF and ON. The highest reading should be documented or used for exception reporting.

Typical electrical safety test set-up.

 ©University of Vermont, Rev. 2 – Confidential

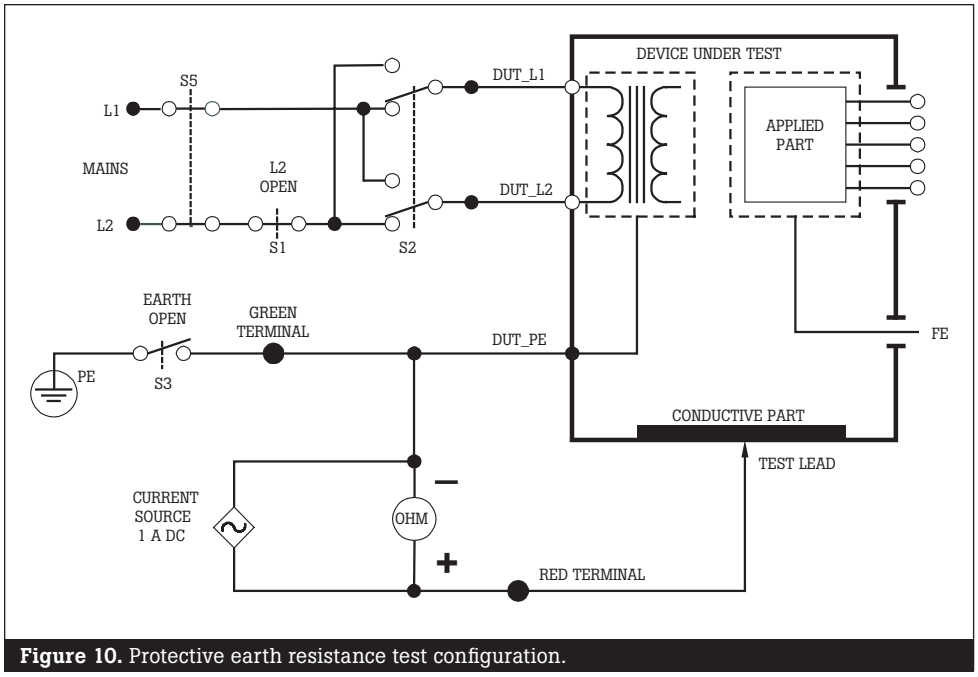


Figure 10. Protective earth resistance test configuration.

Switch		Action
Diagram Reference	ESA601 Name	
S1	Neutral	—
S2	Polarity	—
S3	Earth	Open
S5	—	—

Ground wire resistance

Insert the medical equipment electrical power plug into the ESA power receptacle. If this is a permanently-wired device, a ground connection at the same potential as the device under test needs to be located. A ground wire must be attached to the ESA ground input. Devices that are located in rooms with isolated power should be tested on grounded distribution systems.

Zero the test lead resistance by connecting the RED lead to the ESA ground point (e.g. ESA 601—PE TEST POINT) and pressing the Zero button.

Attach the RED ground lead to the device under test (DUT) chassis grounding point. Activate the control for ground wire resistance measurement and record the reading or document by exception only.

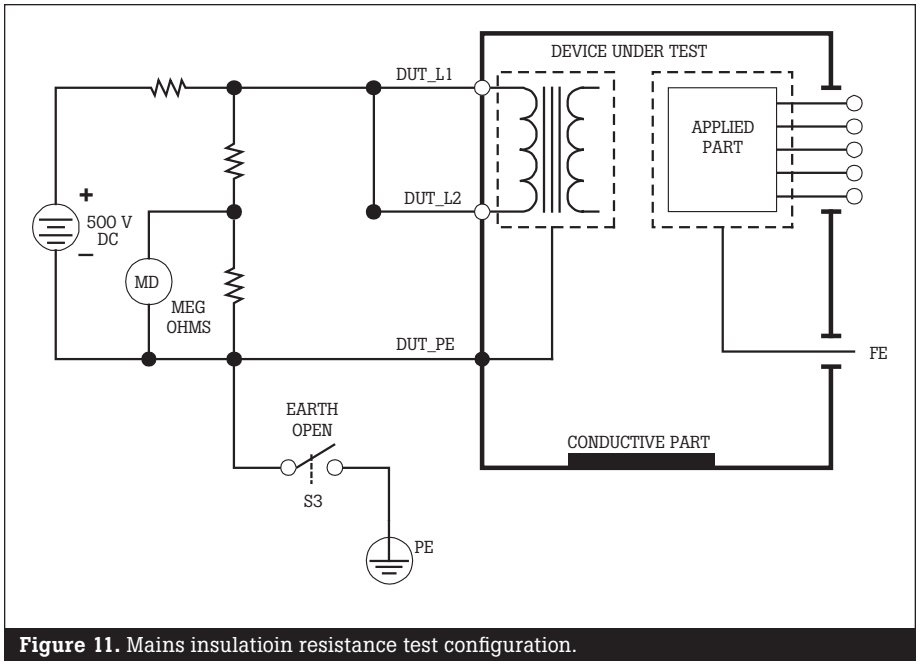


Figure 11. Mains insulatioin resistance test configuration.

Insulation tests

Remove the **red** test lead from the chassis grounding point. Switch the function switch to measure insulation first from earth ground, then from the patient applied part.

Switch		
Diagram Reference	**ESA601 Name**	**Action**
S3	Earth	Open

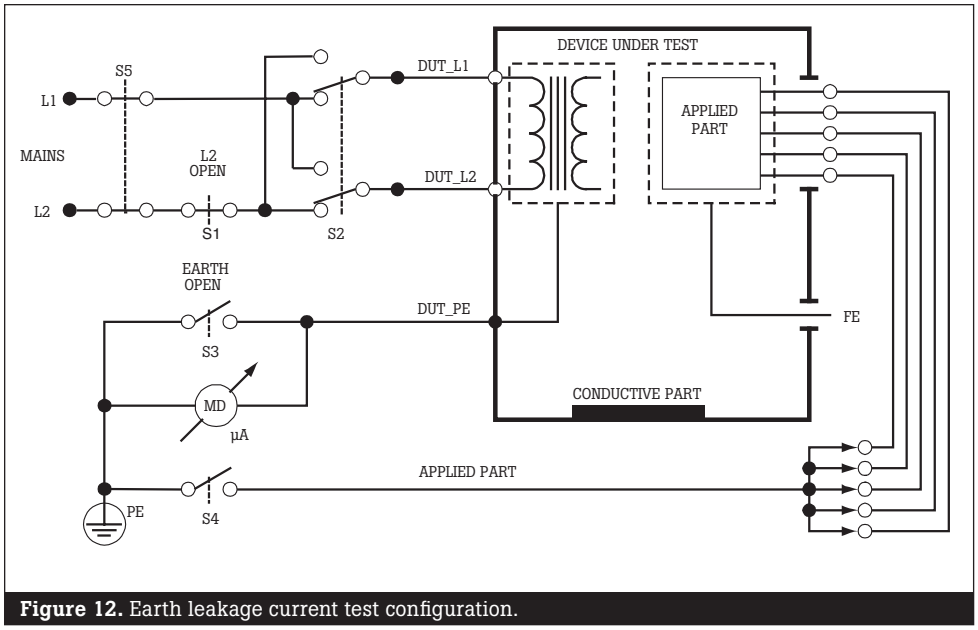


Figure 12. Earth leakage current test configuration.

Switch		
Diagram Reference	**ESA601 Name**	**Action**
S1	Neutral	Variable
S2	Polarity	Variable
S3	Earth	Open
S4	Applied parts selection knob	Variable
S5	—	—

Earth electrical leakage current

Measure the earth leakage current by switching the function switch to the Earth Leakage setting and following the ESA procedure. Make measurement without the **red** lead attached to the device. The measurement should be made under Normal and Reverse Polarity. Ensure the ESA is not quickly switched between Normal and Reverse Polarity. Record the reading or document by exception.

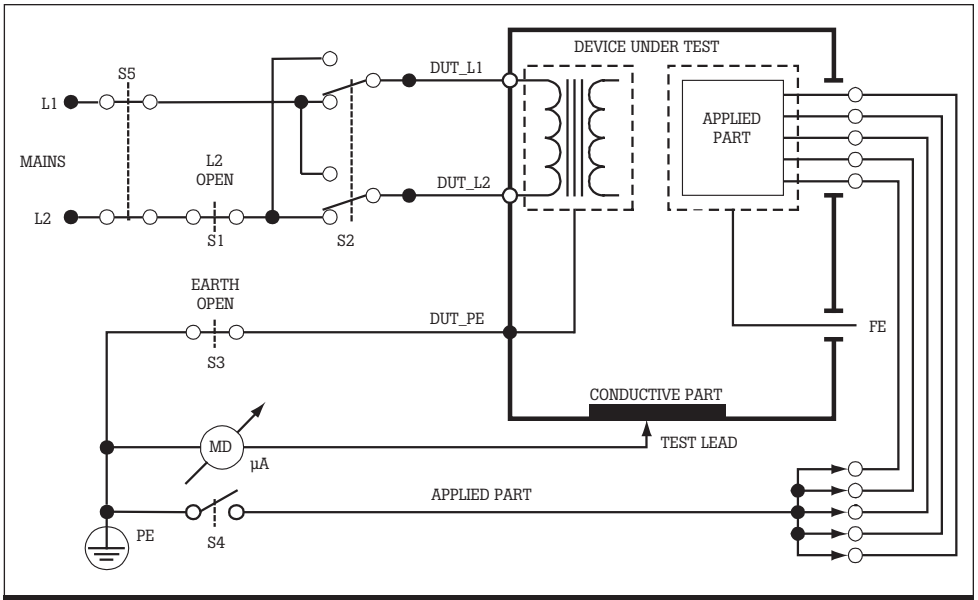


Figure 13. Enclosure leakage current test configuration.

Chassis electrical leakage current

Measure the chassis leakage current following the ESA procedure. Make measurement with the **red** lead attached to the device. The measurement should be made under Normal and Reverse polarity. Ensure the ESA is not quickly switched between Normal and Reverse polarity. Record the reading or document by exception only.

Switch		
Diagram Reference	**ESA601 Name**	**Action**
S3	Earth	Open

Chassis/enclosure leakage current test.

 ©University of Vermont, Rev. 2 – Confidential

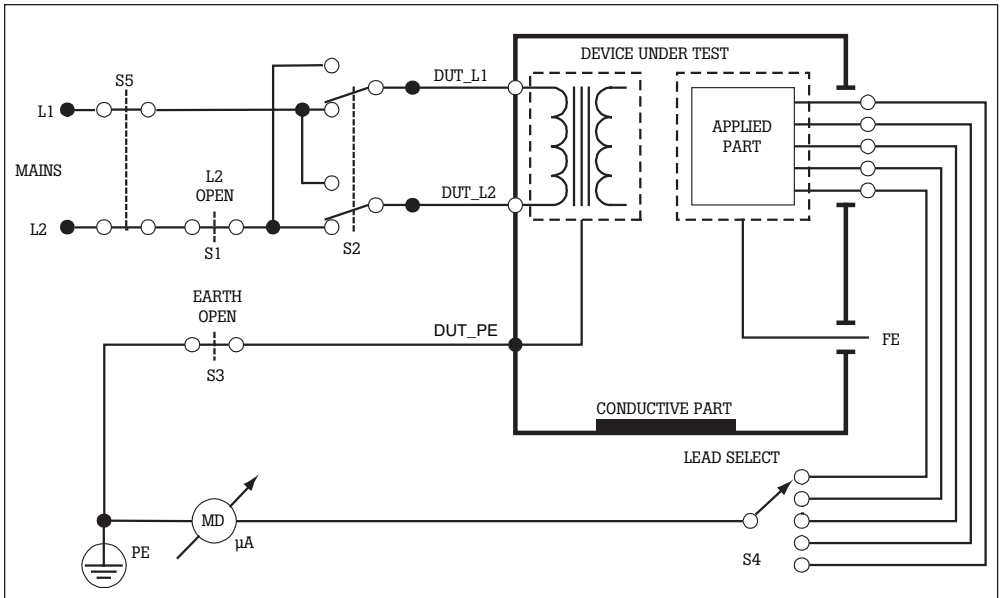


Figure 14. Patient leakage current test configuration.

Switch		
Diagram Reference	**ESA601 Name**	**Action**
S1	Neutral	Variable
S2	Polarity	Variable
S3	Earth	Variable
S4	Applied parts selection knob	Variable
S5	—	—

Chassis/enclosure leakage current test.

Patient applied part leakage current

Ensure the patient applied leads are attached to the appropriate connectors on the ESA (e.g. see Figure 8) per the ESA manual. Switch the function switch to Patient Lead Leakage or Applied Parts Leakage per the ESA instructions. Make measurements with the **red** lead attached to the device. The measurement should be made under Normal and Reverse polarity. Ensure the ESA is not quickly switched between Normal and Reverse polarity. The test should be performed by selecting **all** leads connected together and individual leads measured in respect to ground. Record the reading or document by exception only.

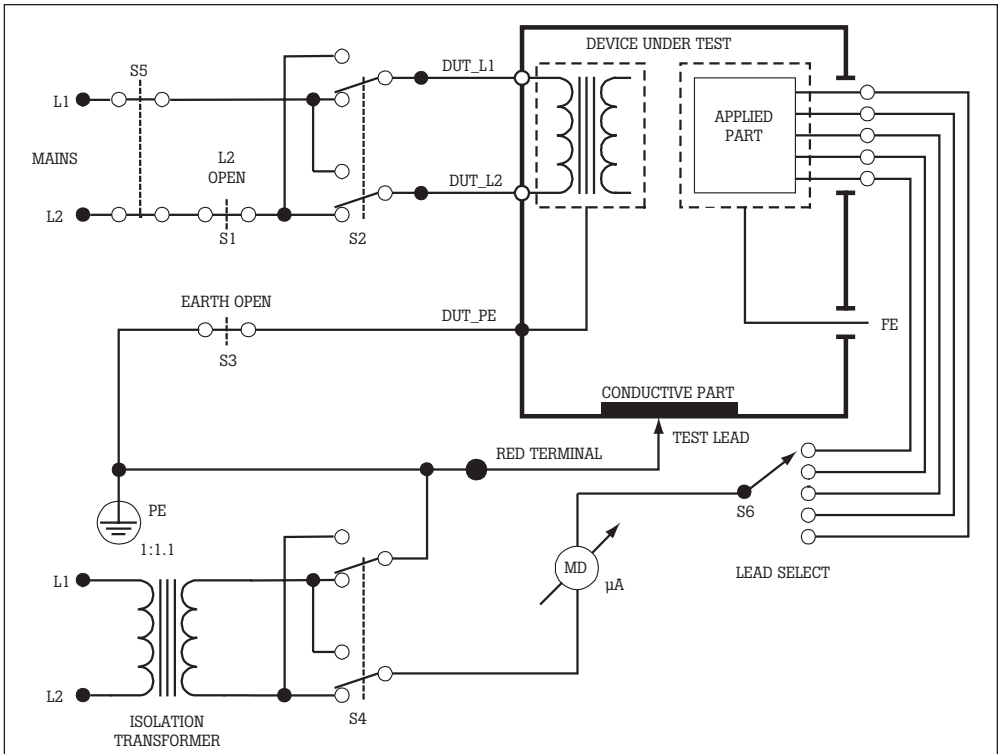


Figure 15. Mains on applied parts leakage current test configuration.

Lead isolation test/mains on applied parts leakage

This test applies the power line or mains voltage to the patient applied parts so caution should be taken in not to come in contact with the patient applied parts during this test. Ensure the Patient Applied Leads are attached to the appropriate connectors on the ESA (e.g. see Figure 8) per the ESA manual. Switch the function switch to Patient Lead Leakage or Applied Parts Leakage per the ESA instructions. Make measurements with the RED lead attached to the device. The measurement should be made under Normal and Reverse polarity. Ensure the ESA is not quickly switched between Normal and Reverse polarity. The test should be performed by selecting ALL leads connected together and individual leads measured in respect to ground. Record the reading or document by exception only.

Switch		
Diagram Reference	ESA601 Name	Action
S1	Neutral	Closed
S2	Polarity	Variable
S3	Earth	Closed
S4	M.A.P./500 V	Variable
S5	—	—
S6	Applied parts selection knob	Variable

Return to service

Before returning to use, return any controls that were adjusted to their original settings. Plug in the power cord to ensure the battery remains charged.

CHAPTER 6: Equipment inspection procedures

This section contains preventive maintenance and inspection procedures for common medical equipment. Each procedure will list the necessary test equipment, estimated time for inspection, and an inspection check list that can be used for documentation. The checklist is broken up into four categories, physical condition, electrical safety, preventive maintenance, and performance inspection. A test form for general equipment is given for reference.

General equipment procedure

Estimated time: 20 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
Other equipment as necessary

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Calibrate to manufacturer's specifications	
			Check all fluid levels	
			Replace battery every 24 months	
			Clean exterior	
			Lubricate as required	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify unit operates within manufacturer's specifications	
			Operates on battery power	
			Audible alarms	
			Visual alarms	
			Remote alarms	
			Complete model-specific performance testing	

 ©University of Vermont, Rev. 2 – Confidential

Physical condition and electrical safety are general maintenance requirements that apply to all medical equipment. This information will appear on all checklists and should be performed during all inspections. These general maintenance tasks will not be discussed in the specific device procedures.

Physical condition

These tasks check the physical condition of the equipment. These tasks should be performed for all medical equipment.

- **Device is clean and decontaminated:** Ensure the equipment has been cleaned following patient use. Examine the exterior of the unit for cleanliness. If there are signs of blood or other spilled liquids, the device should be cleaned per the hospital's equipment disinfection policy and the manufacturer's approved cleaning instructions.
- **No physical damage to case, display, mounts, cart, or components:** Examine the device for general physical condition. Ensure plastic housings are intact and that all assembly hardware is present and tight. Examine the exterior for cracks and chips. Check that shelves and brackets are secure. Check the condition of castors and ensure they turn and swivel as appropriate. Check the operation of the brakes.
- **Switches and controls operable and correctly aligned:** Ensure all switches, buttons, knobs, and other controls are operable. Verify knobs are properly aligned with markings on the control panel.
- **Display intensity adequate for daytime use:** Verify all lights, LEDs, and displays can be easily seen in ambient light. Displays should be able to be read easily under normal operating conditions.
- **Control numbers, labeling, and warnings present and legible:** Ensure all control numbers, device labels, warning labels, or other labels can be easily read. Verify control numbers and inspection stickers do not cover up any cautions, warning labels, or other device information.
- **Inlets and hoses:** Check the condition of all external tubing and hoses. Ensure they are not cracked or kinked. Check the general condition of the connectors. Look for damage such as stripping or cross threading. Verify that connectors are tight.
- **Power cord, patient and accessory cables, charger:** Check the physical condition of the power cord. Look for cuts, frayed wires, and missing insulation. Check the physical condition of the plug, looking for bent or loose prongs. Ensure strain reliefs are intact. Check the physical condition of cables, looking for frayed wires and loose or bent connections. Ensure connections are clean and free of corrosion and build up such as gel or hair. Verify that disposable accessories are within their expiration dates.
- **Filters and vents clean:** Ensure filters and vents are free of dust and other build up. Pay special attention to cooling fans. Clean or replace filters as necessary.

Electrical safety

These tasks check the electrical safety of the equipment and are important to prevent a shock to the patient. Follow the procedures given in Chapter 5, Electrical Safety. Measure ground wire resistance, chassis leakage. Measure current leakage to patient leads if applicable. Electrical safety should be checked for all medical equipment.

- **Device specific tasks**
  Preventive maintenance and performance inspection include maintenance tasks and testing criteria that are specific for each device type. These tasks should be performed in addition to the general physical and electrical safety tests.
  As a general guideline, rechargeable batteries should be replaced every 24 months. Certain batteries in low-use situations such as automatic external defibrillators may last longer. The manufacturer battery replacement schedule should be followed if provided in the documentation. Electrical safety checks should be performed following a battery replacement. Always verify the operation of the device before replacing the battery. A functional test should be performed following battery replacement.

These procedures are written for general device types. Check the equipment's service manual for any additional model-specific tests and maintenance.

Preventive maintenance

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Returning the device to service: Upon completion of maintenance, all controls should be returned to their previous clinical settings. Return all alarm limits adjusted during the functional test to their original locations. Adjust the alarm volume to an audible level. The alarms should be able to be heard easily in the normal operating environment. If the device will not immediately be returned to use, make sure the power cord is plugged in to ensure the battery remains charged and the equipment is ready for use.

Apnea monitor

Apnea is defined as the absence of breathing. An apnea monitor is designed to detect this condition. The apnea monitor senses by measuring changes in the electrical impedance of the thoracic cavity during respiration. Typically, electrodes are attached to the patient with lead wires connected to the monitor. The monitor will usually display the patient's heart rate and respiration rate, with the limits of these parameters adjustable by the user. An audible alarm will sound when the alarm limits are exceeded or if the monitor or when an apnea condition is detected. These types of monitors are typically used to monitor high-risk infants.

Recommended functional test frequency: semiannual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	3
Device is used to deliver direct treatment to the patient	4	
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	
Device failure could result in severe injury to, or death of, patient or user	4	4
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	3
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant History	1	
A significant history of incidents exists	2	2
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		13
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		2

Apnea monitor procedure

Estimated time: 25 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
MPS450 Multiparameter Simulator (or equivalent)
Stopwatch or watch with a second hand

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Replace battery every 24 months	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify unit operates on battery	
			Heart rate accuracy	± 5 %
			Respiratory rate accuracy	± 5 %
			Apnea alarm function	
			Apnea alarm delay time	± 20 %
			60 BPM rejection of ECG artifact	
			Alarm function	
			Complete model-specific performance testing	

 ©University of Vermont, Rev. 2 – Confidential

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance, chassis leakage, and lead leakage.

Preventive maintenance

Replace battery: The battery should be replaced every 24 months. Replace if necessary.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Verify unit operates on battery: Check that the ac power indicator is lit up when the power cord is plugged into an outlet. Unplug the ac power cord and perform the remainder of the functional test on battery power. The ac power indicator should go out when the power cord is unplugged and the battery indicator should light up. Be sure to plug the power cord back in at the conclusion of the test.

Heart rate accuracy, respiratory rate accuracy: Connect the patient leads to the lead connectors on the MPS450. The respiratory signal from the MPS450 is sent to the left arm (LA) lead on the default setting. Change the respiratory signal to the left leg (LL) if necessary. From the main menu, press '0' (SETUP), press the leftmost blue arrow key for 'RESP', and then again for 'LEAD'. This will toggle the respiratory lead from LA to LL. For most purposes, the respiratory lead can be left on left arm.

Set the heart rate on the MPS450 to 120 bpm. Press '1' (NSR), and then use the soft keys marked 'UP' and 'DOWN' to change the heart rate to 120 bpm.

Set the respiration rate to 60 breaths/min. Press '2' (RESP) and then use the soft keys to change the respiration rate.

The heart rate and respiration rate should be within 5 % of the set rates. For a simulated heart rate of 120 bpm, the displayed rate should be between 114 bpm and 126 bpm. For a respiration rate of 60 breaths/min, the displayed respiration rate should be between 57 breaths/min and 63 breaths/min.

Apnea alarm function: On the MPS450, press the button marked '2' (RESP). To simulate an apnea condition, press the rightmost soft key button 'APNE'. Use the soft keys marked 'PREV' and 'NEXT' to cycle through the apnea durations and select 'CONTINUOUS'. Press the soft key labeled 'RUN' to start the apnea condition. To stop the apnea condition and return to normal respiration, press the soft key labeled 'STOP'. The alarm should sound for an apnea condition. Most monitors will alarm within 30 seconds.

Apnea alarm delay time: Simulate an apnea condition as described in the step above. Set the apnea duration to continuous. Start the apnea simulation by pressing the soft key labeled 'RUN' and begin timing on the stopwatch. Stop timing when the apnea alarm sounds. Press the soft key labeled 'END' to return to normal respiration and silence the alarm. Compare the actual time for the alarm to sound with the monitor's alarm delay. The time should be with 20 % of the delay setting. For an apnea delay of 30 seconds, the alarm should sound within 36 seconds.

60 bpm rejection of ECG artifact: This test checks the coincidence circuit designed to reject detected breaths that may be erroneously detected QRS complexes from the ECG signal.

Press '2' (RESP) to enter the Respiration menu on the MPS450. Set the respiration rate to 60 breaths/min. Press '1' (NSR) to enter the Normal Sinus Rhythm menu. Set the heart rate to 60 bpm. The monitor should alarm. Set the heart rate back to 120 bpm.

Alarm function: Check that all alarms are functional and that the volume is adequately loud. Ensure appropriate visual indicators are functioning.

Check heart rate and respiration rate alarms separately. Note the alarm settings on the monitor. Press '1' (NSR) on the MPS450 to enter the Normal Sinus Rhythm menu on the MPS450. Bring the heart rate down to just below the monitor's low heart rate limit. The alarm should sound. Increase the heart rate above the low alarm point. Clear the alarm if necessary. Increase the heart rate to just above the high heart rate limit. Note that the alarm sounds when the heart rate increases beyond the high alarm limit. Set the heart rate back to 120 bpm and clear any alarms.

Press '2' (RESP) to enter the Respiration menu. Repeat the process for the respiration rate as done for the heart rate above. Ensure the monitor alarms when the respiration rate falls below the set low respiration limit and above the high respiration limit. Set the respiration rate to 60 breaths/min and clear any alarms.

Check the function of the accidental power off alarm. Apnea monitors used on infants are often equipped with a 'sibling alarm' that sounds when the monitor is turned off accidentally. These monitors will require a key sequence to power off without sounding an alarm, such as holding the reset button while turning the power off. Check the operator's manual for the device's specific operation. To check the alarm, press the power button without performing the power-off button sequence. The monitor should shut down, but an alarm will sound. Follow the instructions in the operator's manual to clear this alarm.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any alarms that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions. Plug in the power cord to ensure the battery remains charged.

Aspirator

An aspirator is sometimes known as a suction pump or a vacuum. It uses suction to remove gas, fluid, tissue, or other materials from a body cavity. An aspirator typically consists of a suction pump, a collection container, tubing, a pressure gauge, and a means for adjusting the vacuum pressure. The motorized suction pump creates a vacuum in the suction tubing. When the tubing is inserted into a body cavity, material is sucked through the tubing and deposited into the collection container.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	4
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	2
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	1
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		10
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

Aspirator procedure

Estimated time: 20 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent) DPM 4 Pressure Meter (or equivalent)
Stopwatch or watch with a second hand Tubing and connectors to connect to DPM 4

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Replace battery every 24 months	
			Replace filters	
			Lubricate motor	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify unit operates on battery	
			Vacuum gauge accuracy	± 10 %
			Maximum vacuum Thoracic, low volume: Emergency, surgical, tracheal, uterine: Breast pump:	 > 40 mmHg > 400 mmHg > 200 mmHg
			Vacuum rise time Thoracic: Emergency, Surgical, Tracheal: Uterine: Breast pump:	 < 4 sec/30 mmHg < 4 sec/300 mmHg < 3 sec/30 mmHg < 2 sec/150 mmHg
			Complete model-specific performance testing	

 ©University of Vermont, Rev. 2 – Confidential

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage.

Preventive maintenance

Replace battery: The battery should be replaced every 24 months. Replace if necessary.

Replace filters: Inspect filters and replace as necessary. Refer to the device service manual for filter replacement.

Lubricate motor: Follow the manufacturer's instructions in the service manual for lubricating the pump motor. Not all motors will need to be lubricated.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Verifying aspirator vacuum accuracy with the DPM 4.

Performance inspection

Verify unit operates on battery: Check that the ac power indicator is lit when the power cord is plugged into an outlet. Unplug the ac power cord and perform the remainder of the functional test on battery power. The ac power indicator should go out when the power cord is unplugged and the battery indicator should light. Be sure to plug the power cord in at the conclusion of the test.

Vacuum gauge accuracy: Turn on the DPM 4. The DPM 4 defaults to pressure units in mmHg. If the pressure gauge is in another unit, press the soft key labeled 'UNIT' and then select the desired units. Most aspirators measure vacuum in mmHg. The DPM 4 should read '0.0' mmHg when the pressure port is open to atmosphere.

Connect the aspirator to the pressure port on the front of the DPM 4. This connector is a male leur lock connector. The connection from the aspirator should come from the port intended for the patient tubing.

Turn on the aspirator and adjust the vacuum to a low setting. Slowly increase the vacuum across its range up to the maximum setting. Compare the vacuum gauge reading with the measured vacuum from the DPM 4. The gauge reading should be within 10 % of the measured vacuum. For a vacuum gauge reading of 300 mmHg, the measured vacuum should be between 270 mmHg and 330 mmHg.

Maximum vacuum: Disconnect the suction tubing from the DPM 4 and occlude the suction tubing. The tubing can be occluded with a stopcock in the off position or by simply covering the tubing with your thumb. Adjust the suction to its maximum setting. The accuracy of the vacuum gauge must be verified prior to this test. The values on the test form are guidelines based on common practice. Refer to the aspirator's operator manual for its actual performance capability. If the measured vacuum is low, look for air leaks, particularly in collection bottle caps and hoses. Release the occlusion on the tubing.

Vacuum rise time: With the aspirator set to its maximum setting, occlude the suction tubing. Use a stopwatch or a watch with a second hand to measure the time it takes to reach the vacuum level indicated on the test form. Thoracic aspirators should reach 30 mmHg in less than 4 seconds. Emergency, surgical, or tracheal aspirators should reach 300 mmHg in less than 4 seconds. Uterine aspirators should reach 300 mmHg in less than 3 seconds. Breast pumps should reach 150 mmHg in less than 2 seconds. Again, these are general guidelines based on common practice. Refer to the aspirator's operator manual for its actual performance capability.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return the suction setting to its original setting. Plug in the power cord to ensure the battery remains charged.

 ©University of Vermont, Rev. 2 – Confidential

Cardiac output unit

A cardiac output unit measures the volume of blood pumped by the heart during a period of time, typically measured in liters per minute (L/min). Cardiac output represents the volume of blood that is delivered to the body is an indicator of overall cardiac status and tissue perfusion. Blood flow from the heart is measured using the thermal dilution technique in which a cold solution is injected upstream of the heart and the temperature differential is monitored on the downstream side. A balloon catheter is inserted through the heart. The temperature of the surrounding blood is measured through a thermistor located near the tip of the catheter. Once the catheter is inserted, ice water is injected through the catheter and emerges from a small hole approximately 12 inches before the end of the catheter. The cardiac output unit processes the signal from the thermistor and displays a thermal dilution curve from which cardiac output and other hemodynamic parameters such as stroke volume can be derived.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	3
Device is used to deliver direct treatment to the patient	4	
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	3
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	1
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		10
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

Cardiac output monitor procedure

Estimated time: 20 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date:_____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
MPS450 Multiparameter Simulator (or equivalent)
Cardiac output adapter box
Cables to connect to cardiac output monitor

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Performance testing				
			Verify accuracy of blood temperature	37 °C ± 0.2 °C
			Verify cardiac output accuracy	
			Complete model–specific performance testing	

 ©University of Vermont, Rev. 2 – Confidential

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage.

Performance inspection

Verify accuracy of blood temperature: Adjust the settings on the cardiac output monitor as follows. Set the catheter type/size to Baxter Edwards, 93a-131-7f. Set the calibration coefficient to 0.595. Set the injectate volume to 10 cc. Set the injectate temperature to 24 °C.

Connect the cardiac output box to the 'CO/TEMP' port on the right hand side of the MPS450. Connect the blood temperature thermistor cable from the cardiac output monitor to the small 4 pin connector on the cardiac output adapter. Connect the injectate temperature from the cardiac output monitor to the large 4-pin connector on the cardiac output box located just above the resistance trimpot.

Connecting the cardiac output monitor to the MPS450.

Turn on the MPS450. Press the button labeled '8' ('CO') to enter the cardiac output menu.

The blood temperature displayed on the cardiac output monitor should read 37 °C ± 0.2 °C.

Verify cardiac output accuracy: With the cardiac output monitor and MPS450 set up as above, enter the cardiac output menu on the MPS450 by pressing '8' (CO). Press the soft key labeled 'INJ' to toggle the injectate temperature between 0 °C and 24 °C. Set the injectate temperature to 24 °C.

Turn the trimpot on the cardiac output box until the injectate temperature on the cardiac monitor reads 24 °C.

The simulated flow rate on the MPS450 can be set to 2.5 L/min, 5.0 L/min and 10.0 L/min by pressing the soft keys labels 'PREV' and 'NEXT' to scroll through the values. The cardiac output should be checked at each of these settings.

Set the volume on the MPS450 to 2.5 L/min. Initiate a cardiac output measurement on the monitor. Press the soft key labeled 'RUN' on the MPS450 to start the simulation. If you need to end the simulation before the cardiac output calculation is complete, press the soft key labeled 'STOP'. Repeat this measurement for the 5.0 L/min and 10.0 L/min rates.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return the cardiac output monitor to its original settings.

Central station

Central stations are monitors that are designed to be positioned in a central location, usually at a nurse's station and consolidate information from individual bedside and telemetry monitors. The central station usually displays an ECG waveform for each patient being monitored, and also any alarms that are triggered. Central stations typically consist of one or more displays, a computer that runs the central station, speakers for audible alarms, and a recorder for printing ECG strips. Bedside monitors will be connected to the central station computer through the hospital's network. If telemetry transmitters are used for remote monitoring, an antenna system and receivers will be necessary for receiving the radio signal. Central stations are used for remote monitoring of patients in one or more areas of a hospital. They do not replace bedside monitors.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	3
Device is used to deliver direct treatment to the patient	4	
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	3
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	1
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		10
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

 ©University of Vermont, Rev. 2 – Confidential

FLUKE®
Biomedical

Central station monitoring system procedure

Estimated time: 35 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
MPS450 Multiparameter Simulator (or equivalent)
Index 2 SpO_2 Simulator (or equivalent)
Vacuum or canned air for clearing dust from cooling fans

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Clean dust from cooling fans	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify display is clear and legible	
			Verify monitoring capabilities of hard wired monitors	
			Verify monitoring capabilities of telemetry transmitters	
			Verify recorder accuracy	± 4 %
			Verify operation of alarms	
			Complete model-specific performance testing	

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. The central station will not be able to be removed from power for testing and will need to be tested as permanently installed medical equipment.

Preventive maintenance

Clean dust from cooling fans: The computers that run central station monitoring systems are often situated under desks. As the cooling fans accumulate a lot of dust and debris, they can become clogged and lead to overheating of the computer system. Use a small vacuum or a canned air to remove dust from the fans and vents. A vacuum is preferred over compressed air, as it will not blow dust around the patient care area.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Verify display is clear and legible: The monitor should be clear and bright enough to read. Look for distortion around the edges of the screen.

Verify monitoring capabilities of hard-wired monitors: Connect the MPS450 to a monitor following the instructions given in the Patient Monitor procedure. At a minimum simulate a heart rate and respiration. Attach the ECG lead wires to the lead connectors on the left side of the MPS450. The MPS450 will default to a normal sinus rhythm of 80 bpm.

Admit a test patient in this bed on the central station. Verify that the central station displays the ECG wave, heart rate, and other monitored parameters. Discharge the test patient.

Verify monitoring capabilities of telemetry transmitters: Connect the ECG leads of the telemetry transmitter to the lead connections on the left side MPS450. Press '1' (NSR) to enter the normal sinus rhythm menu. Set the heart rate to 80 bpm. If the telemetry has SpO_2 capabilities, connect the finger probe to the Index 2 Pulse Oximeter Simulator as described in the Pulse Oximeter Procedure.

Ensure that a battery is installed in the telemetry transmitter. Admit a test patient on this telemetry channel. Verify that the central station displays the ECG rhythm and heart rate. Discharge the test patient when finished. The process will need to be repeated for each telemetry transmitter.

Verify recorder accuracy: With a test patient admitted to the central station and the ECG leads connected to the MPS450 as above, press '1' (NSR) on the MPS450. Set the heart rate to 60 bpm. Initiate strip record on the central station.

Measure the distance between the peaks of the QRS complex. With a recorder speed of 25 mm/sec, the QRS peaks should be between 24 mm and 26 mm apart.

Verify operation of alarms: Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

Note the alarm settings on the central station. Press '1' (NSR) to enter the Normal Sinus Rhythm menu. Bring the heart rate down to just below the monitor's low heart rate limit. The alarm should sound. Increase the heart rate above the low alarm point. Clear the alarm if necessary. Increase the heart rate to just above the high heart rate limit. Verify that the alarm sounds when the heart rate increases beyond the high alarm limit. Set the heart rate back to 80 bpm and clear any alarms.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Discharge any test patients. Return any alarms that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions.

Compression unit

Compression units are designed to apply and release pressure on a patient's limbs in order to facilitate the return of blood through the veins. They are used to reduce the risk of deep vein thrombosis during long periods of immobilization, which can lead to pulmonary embolism. Compression units are also used during and immediately following surgery to minimize venous stasis. A compression unit typically consists of an air compression pump, a pressure control mechanism, a timing mechanism, tubing, and cuffs that wrap around the patient's limbs. Air is pumped through the tubing into the cuffs until the pressure inside the cuff reaches a set pressure. The cuff remains inflated at the set pressure for a set period of time. Pressure is then relieved from the cuff and the cuff remains deflated for another set period of time. The compression unit will continuously repeat this cycle of inflation and deflation.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	4
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	2
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	1
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		10
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

Compression unit procedure

Estimated time: 20 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
DPM 4 Pressure Meter (or equivalent)
Stopwatch or watch with a second hand
Tubing and connectors to connect to DPM 4
Compression set
PVC pipe to attach compression set to

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Replace battery every 24 months	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify unit operates on battery	
			Pressure accuracy	± 2 %
			Timing cycle accuracy	± 2 %
			Alarm function	
			Complete model-specific performance testing	

 ©University of Vermont, Rev. 2 – Confidential

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage

Preventive maintenance

Replace battery: The battery should be replaced every 24 months. Replace if necessary.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Verify unit operates on battery: Check that the ac power indicator is lit when the power cord is plugged into an outlet. Unplug the ac power cord and perform the remainder of the functional test on battery power. The ac power indicator should go out when the power cord is unplugged and the battery indicator should light. Be sure to plug the power cord in at the conclusion of the test.

Pressure accuracy: A tubing set that can connect to the compression unit and to the DPM 4 will be needed for this test. A simple test set can be constructed from a disposable compression set. Cut the tubing a short distance from the connector for the compression unit. Insert a luer connector into the tubing to connect to the DPM 4. If the compression set has multiple inflation tubes, occlude the remaining open tubing using tie-wraps.

Connect the test set to the compression unit. The DPM 4 defaults to pressure units in mmHg. If the pressure gauge is in another unit, press the soft key labeled 'UNIT' and then select the desired units. Most compression units measure pressure in mmHg. The DPM 4 should read '0.0' mmHg when the pressure port is open to atmosphere. Connect the test set to the pressure port of the DPM 4.

Start the compression cycle on the compression unit. Measure the reading using the DPM 4 and compare this value with the display on the compression unit. If the compression unit has multiple settings, measure the pressure readings throughout its range. The pressure displayed on the compression unit should be within 2 % of the pressure measured on the DPM 4. For a pressure reading of 45 mmHg, the measured pressure should be between 44 mmHg and 46 mmHg.

Testing pressure accuracy of a compression unit with the DPM 4.

Timing cycle accuracy: Disconnect the DPM 4 and test tubing from the compression unit and connect a complete compression set. For testing, attach the compression set to a piece of PVC pipe or other rigid pipe to simulate a limb. Start the compression cycle. Use a stopwatch or a watch with a second hand to measure the length of time the pressure is held. When the compression unit deflates, measure the length of time before the next inflation. Compare the measured times to the compression unit's setting. The measured time should be within 2 % of the set time.

Alarm function: Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return the compression cycle setting to its original setting. Plug in the power cord to ensure the battery remains charged.

Defibrillator

Defibrillators deliver electric impulse to the heart through the chest wall in order to restore a normal rhythm in patients experiencing ventricular fibrillation or ventricular tachycardia. The high electrical energy stops the independent action of the individual muscle fibers, so that the natural pacemaker of the heart can take over. A set charge is generated and is delivered through a set of paddles or disposable defibrillation electrodes through the chest wall. The defibrillator's output energy is typically selectable from 0 J to 360 J. Most defibrillators also include an electrocardiograph to monitor the patient's rhythm. Some defibrillators include a pacer function. Electrical impulses are delivered to the heart, causing the heart to contract. This is used for emergency treatment of asystole, severe bradycardia, implantable pacemaker failure, or other conditions requiring emergency cardiac pacing.

Recommended functional test frequency: semiannual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	4
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	
Device failure could result in severe injury to, or death of, patient or user	4	4
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	
A significant history of incidents exists	2	2
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		13
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		2

Defibrillator procedure

Estimated time: 30 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date:_____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
Impulse 4000 Defibrillator and Pacer Analyzer (or equivalent)
MPS450 Multiparameter Simulator (or equivalent)
Ohmmeter (Can be part of a multimeter, such as the Fluke 73 series digital multimeter)
Cables and connectors to connect defibrillator to analyzer

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC, < 500 µA SFC
			Patient leakage current	< 100 µA B and BF, < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF, < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Replace battery every 24 months	
			Verify electrodes, gel and paddles are stored with the defibrillator and are within expiration dates	
			Verify proper time and date, correct if necessary	
			Complete model-specific preventive maintenance	

continued on page 61

 ©University of Vermont, Rev. 2 – Confidential

continued from page 60

Test Result				
Pass	Fail	N/A		
Performance testing				
			Verify unit operates on battery	
			Paddle continuity	≤ 0.15 Ω
			Heart rate accuracy	± 5 %
			Recorder speed	± 4 %
			Verify operation of alarms	
			Output accuracy	± 15 %
			Output energy at maximum setting for 10 charge cycles	± 15 %
			Charge time after 10 discharge cycles	≤ 15 sec
			Energy after 60 sec of full charge	≥ 85 %
			Internal discharge function	
			Synchronizer operation	≤ 60 msec
			Pacer output accuracy	± 10 %
			Pacer rate accuracy	± 5 %
			Demand-mode sensitivity	
			Complete model-specific performance testing	

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance, chassis leakage, and lead leakage.

Preventive maintenance

Replace battery: The battery should be replaced every 24 months. Replace if necessary. Verify electrodes and defibrillator gel or disposable paddles are stored with the defibrillator and are within expiration dates: Verify that ECG electrodes are stored with the unit. If hard paddles are used, verify that defibrillator gel is stored with the unit. The conductive gel should be for use with defibrillators and lotion, skin lubricant, or ultrasound gel should not be used. If hard paddles are not used, verify that disposable pads are stored with the unit. Check the expiration date on the electrodes, gel, and disposable paddles.

Verify proper time and date. Correct if necessary: Verify the time and date displayed on the defibrillator is correct. If the time and date is not displayed on the defibrillator monitor, print a strip from the recorder. The time and date should appear on the printed strip. Correct the time and date as necessary.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Verify unit operates on battery: Check that the ac power indicator is lit when the power cord is plugged into an outlet. Unplug the ac power cord and perform the remainder of the functional test on battery power. The ac power indicator should go out when the power cord is unplugged and the battery indicator should light. Be sure to plug the power cord in at the conclusion of the test.

Paddle continuity: Connect the ohmmeter between a paddle and the appropriate pin on the paddle connector. The resistance should not be higher than 0.15 Ω. Repeat for the other paddle. This step can be skipped if only disposable paddles are used.

Heart rate accuracy: Connect the ECG leads to the lead connectors on the Impulse 4000. On the Impulse 4000, press F3 'ECG' to enter the ECG menu. Press F1 'NORM' to select a normal sinus rhythm. Press F2 '60' to set the heart rate to 60 bpm. On the defibrillator, set the ECG source to Lead II.

The heart rate should be within 5 % of the set rate. For a simulated heart rate of 60 bpm, the displayed rate should be between 57 bpm and 63 bpm. Set the heart rate on the Impulse 4000 bpm to 120 bpm. The displayed heart rate should be between 114 bpm and 126 bpm.

Recorder speed: Set the heart rate on the Impulse 4000 bpm to 60 bpm. Record a strip on the defibrillator. Measure the distance between the peaks of the QRS complex. With a recorder speed of 25 mm/sec, the QRS peaks should be between 24 mm and 26 mm apart.

Verify operation of alarms: Check that all alarms are functional and that the volume is adequately loud. Ensure appropriate visual indicators are functioning.

Note the alarm settings on the defibrillator. Set the low limit to 35 bpm and the high limit 155 bpm. The alarm limits may not be able to be set to these exact values, depending on the defibrillator. If that is the case, set the alarm limits to the next closest value, keeping the low limit above 30 bpm and the high limit below 160 bpm.

Press F3 'ECG' on the Impulse 4000 to enter the ECG menu. Press F1 'NORM' to select a normal sinus rhythm. Set the heart rate to 30 bpm. The alarm should sound. Increase the heart rate to 80 bpm and clear the alarm if necessary. Set the heart rate to 160 bpm. Verify that the alarm sounds when the heart rate increases beyond the high alarm limit. Set the heart rate back to 80 bps and clear any alarms. Return the alarm limits to their previous settings.

Output accuracy: Connect the defibrillator paddles to the paddle contacts on the Impulse 4000. The Apex contact is on the right and the Sternum contact is on the left.

If disposable paddles are being used, you will need a test set to connect from the defibrillator cable to the Impulse 4000. A simple test set can be made from a set of disposable paddles. Cut the pads off of the set leaving the connector and two lengths of wire. Strip the ends of the wires and install banana plugs. Insert the banana plugs into the paddle contacts of the Impulse 4000. Connect the test set to the defibrillator cable.

With the Impulse 4000 set to a heart rate of 80 bpm, set the ECG source on the defibrillator to paddles. View the ECG trace on the defibrillator. If the trace appears upside down, reverse the paddle connections.

Return to the main menu of the Impulse 4000. Press F1 'DEFIB' to enter the defibrillator menu. Press F1 'ENERGY' then F2 'HIGH'. The high setting is for energy output up to 1000 J; the low setting is for measuring 50 J and below.

Measure the energy output of the defibrillator throughout its range. At a minimum, measure the output at the lowest setting, a mid level setting, and the highest setting. The output should be within 15 % of the set energy level. At 360 J, the energy output should be between 306 J and 414 J.

Measuring defibrillator power output.

Output energy at maximum setting for 10 charge cycles: Set the energy on the defibrillator to the maximum setting. Charge the defibrillator and then discharge into the Impulse 4000. Repeat this charge and discharge cycle 10 times. On the tenth shock, the energy output should still be within 15 % of the setting.

Charge time after 10 charge cycles: Measure the charge time on the maximum energy setting after 10 discharge cycles. From the 'DEFIB' menu on the Impulse 4000, select F3 'MEXE'. Press F2 'HIGH' for the high energy range. Connect the defibrillator paddles to the paddle contacts on the Impulse 4000. Press F3 'START' and immediately start charging the defibrillator. When the defibrillator is fully charged, immediately discharge into the Impulse 4000. The energy output and the charge time will be displayed. The charge time should not exceed 15 s.

Energy after 60 sec of full charge: Charge the defibrillator at its maximum setting. Wait 60 seconds and then discharge into the Impulse 4000. The output should be at least 85 % of the energy setting. At a setting of 360 J, the output should be at least 306 J.

Internal discharge function: The defibrillator should have a method of discharging stored energy. Some models have a button on the front panel for this function. Others release the energy after a set time or when the defibrillator is turned off. Check the service manual for specific operation of the internal discharge function. Charge the defibrillator and do not discharge. Allow the energy to be discharged internally. Attempt to discharge into the Impulse 4000. Verify that no energy has been delivered.

Sychronizer operation: Set the ECG source on the defibrillator to Lead II. Put the defibrillator into synch mode. Return to the main menu of the Impulse 4000. Press F1 'DEFIB' to enter the defibrillator menu. Press F2 'CARDIO' for the cardioversion menu and then F2 'HIGH'. Press F1 'NSR' for a normal sinus rhythm. Charge the defibrillator. Press and hold the discharge button(s) on the defibrillator. The delay time should not be more than 60 mSec.

Pacer output accuracy: Connect the ECG leads to the lead connectors on the MPS450. Set the heart rate on the MPS450 to 60 bpm. Press '1' ('NSR'), and then use the soft keys marked 'UP' and 'DOWN' to change the heart rate to 60 bpm. On the defibrillator, set the ECG source to Lead II.

Connect the pacing cable to the defibrillator if necessary. You will need a test set to connect the pacing cable to the Impulse 4000. A test set can be made from the disposable pads as described previously.

From the main menu of the Impulse 4000, press F2 'PACER'. Press F1 'INT50Ω' to select the internal 50 Ω test load. Press F1 'PULSE' to enter the pacer measurement mode. Set the pacing rate on the defibrillator to 120 ppm.

Set the defibrillator output to the minimum setting and start pacing. The ECG wave form should display pacing spikes at approximately the mid point between QRS peaks and on top of QRS peaks. The impulse 4000 will display the pacer output amplitude in mA. Measure the pacer output over its entire range. The measured output should be within 10 % of the set output. For an amplitude setting of 100 mA, the measured output should be between 90 mA and 110 mA.

*****IMPORTANT*****

DO NOT TOUCH THE PADDLE CONTACTS ON THE IMPULSE 4000 WHILE THE DEFIBRILLATOR PACER IS ON. TURN THE PACER OFF BEFORE ADJUSTING OR REMOVING CONNECTIONS.

Pacer rate accuracy: While measuring pacer output, the Impulse 4000 also displays the pulse rate. The measured pulse rate should be within 5 % of the set rate. For a rate of 120 ppm, the pulse rate should be between 114 ppm and 126 ppm. Set the heart rate on the MPS450 to 30 bpm. Measure the pulse rate throughout its range.

Demand-mode sensitivity: Set the heart rate on the MPS450 to 60 bpm. Turn on demand mode on the defibrillator pacer if necessary. Adjust the pulse rate on the pacer to just below 60 ppm. The output should stop. No output should be measured on the Impulse 4000 and pacing spikes should not appear on the ECG trace. Adjust the pulse rate to just above 60 ppm. Pacing should start again.

Connect the ECG leads to the Impulse 4000. From the Pacer menu, press F3 'DEMAND'. With the pacer in demand mode, press F1 'START'. The Impulse 4000 will display the calculated underdrive and overdrive ECG rates.

A havertriangle waveform will be displayed on the ECG trace. Pacing spikes should appear on the ECG trace. Press F2 'OVER' to select the overdrive ECG rate. Verify that the pacing stops with this higher rate. Turn off the pacer and return the output and rate to their previous settings.

Return to service: Before returning to use, return any alarms that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions. Ensure the pacer is turned off and that any settings that were adjusted are returned to their original settings. Plug in the power cord to ensure the battery remains charged and ready for use.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Measuring pacer output with the Impulse 4000.

Electrocardiograph

An electrocardiograph (ECG) records the electrical activity of the heart over time by measuring the changes of electrical potential caused by electrical activity of the heart muscle during the heartbeat. Leads affixed to the patient transmit the electrical signal to the processor, which then produces a graph of the amplitude of the signal versus time as the electrocardiogram. The electrocardiogram is used particularly in diagnosing abnormalities of the heart. Diagnostic ECGs typically have 10 physical lead wires but measures the electrical potential from 12 groups of leads. These are commonly referred to as 12 lead ECGs. In addition, diagnostic ECGs typically contain an interpretation function, where the measured signals of the cardiac activity are analyzed using an internal algorithm. Diagnostic ECGs do not usually have heart rate alarms. An ECG monitor will have 3 or 5 lead wires and is used for monitoring as opposed to diagnosis. ECG monitors will have adjustable heart rate alarms.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	3
Device is used to deliver direct treatment to the patient	4	
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	3
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	1
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		10
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

Electrocardiograph procedure

Estimated time: 25 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
MPS450 Multiparameter Simulator (or equivalent)

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Replace battery every 24 months	
			Clean rollers and paper guides	
			Lubricate motor and paper drive mechanism	
			Verify proper time and date. Correct if necessary	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify unit operates on battery	
			Heart rate accuracy	± 5 %
			Amplitude accuracy	± 5 %
			Recorder speed	± 4 %
			Paper cue	
			Alarm function	
			Complete model-specific performance testing	

 ©University of Vermont, Rev. 2 – Confidential

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance, chassis leakage, and lead leakage.

Preventive maintenance

Replace battery: The battery should be replaced every 24 months. Replace if necessary.

Verify proper time and date. Correct if necessary: Verify that the time and date displayed on the electrocardiograph is correct. If the time and date is not displayed on the monitor, print a strip from the recorder. The time and date should appear on the printed strip. Correct the time and date as necessary.

Electrocardiograph with leads connected to MPS450.

Clean rollers and paper guides: Inspect the rollers and paper guides and remove any debris. Check for bits of torn paper caught in the rollers.

Lubricate motor and paper drive mechanism: Follow the manufacturer's instructions in the service manual for lubricating the motor and paper drive mechanism. Not all motors will need to be lubricated.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Verify unit operates on battery: Check that the ac power indicator is lit when the power cord is plugged into an outlet. Unplug the ac power cord and perform the remainder of the functional test on battery power. The ac power indicator should go out when the power cord is unplugged and the battery indicator should light. Be sure to plug the power cord in at the conclusion of the test.

Heart rate accuracy: Connect the patient leads to the lead connectors on the MPS450. Set the heart rate on the MPS450 to 60 bpm. Press '1' (NSR), and then use the soft keys marked 'UP' and 'DOWN' to change the heart rate to 60 bpm.

The heart rate should be within 5 % of the set rate. For a simulated heart rate of 60 bpm, the displayed rate should be between 57 bpm and 63 bpm. Set the heart rate on the MPS450 to 120 bpm. The displayed heart rate should be between 114 bpm and 126 bpm.

Amplitude accuracy: With the patient leads connected to the MPS450, input a normal sinus rhythm by pressing '1' (NSR). Press the soft key marked 'SEL' to select AMPL. Use the soft keys marked up and down to change the amplitude to 1.0 mV. Set the sensitivity on the electrocardiograph to 20 mm/mV. Record a strip on the electrocardiograph.

Measure the height of the QRS peak. The measured amplitude should be within 5 % of the set amplitude. For an amplitude setting of 1 mV and a sensitivity of 20 mm/mV, the peak height should be between 19 mm and 21 mm.

Recorder speed: Set the heart rate on the MPS450 to 60 bpm. Record a strip on the electrocardiograph. Measure the distance between the peaks of the QRS complex. With a recorder speed of 25 mm/sec, the QRS peaks should be between 24 mm and 26 mm apart.

Paper cue: Verify the operation of the paper cue, if equipped. Initiate a page advance on the electrocardiograph. The paper should stop at the beginning of the next page. If the paper does not stop or stops at an incorrect location, ensure the correct paper is being used with the electrocardiograph. Clean the optical sensor if necessary.

Verify operation of alarms: Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning. Electrocardiographs designed for diagnosis usually do not include hear rate alarms.

Note the alarm settings on the monitor. Press '1' (NSR) to enter the Normal Sinus Rhythm menu. Bring the heart rate down to just below the monitor's low heart rate limit. The alarm should sound. Increase the heart rate above the low alarm point. Clear the alarm if necessary. Increase the heart rate to just above the high heart rate limit. Note that the alarm sounds when the heart rate increases beyond the high alarm limit. Set the heart rate back to 60 bpm and clear any alarms.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any alarms that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions. Plug in the power cord to ensure the battery remains charged.

Electrosurgical unit

Electrosurgical units (ESU) use electrical energy for cutting tissue and for controlling bleeding by causing coagulation using a high-frequency electric current. Tissue resistance to the high-frequency, high-density current results in a heating effect that causes tissue destruction. Electrical current is delivered and received through cables and electrodes. The electrodes may be activated by either a switch on the hand piece holding the electrode, or by a footswitch. An ESU may use a monoploar or a bipolar mode. In monoplar mode, electrical current is delivered to the patient by an active cable and electrode and returns to unit through a return electrode. In bipolar mode, two electrodes, typically the tips of a pair of forceps or scissors, serve as the equivalent of the active and dispersive leads in the monopolar mode.

Recommended functional test frequency: semiannual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	4
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	
Device failure could result in severe injury to, or death of, patient or user	4	4
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	
A significant history of incidents exists	2	2
Manufacturers /regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		13
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		2

Electrosurgical unit procedure

Estimated time: 20 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
QA-ES II Electrosurgery Analyzer (or equivalent)
Cables and connectors to connect ESU to QA-ES II

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Replace filters as necessary	
			Complete model-specific preventive maintenance	
Performance testing				
			Inspect dispersive electrode	
			Operation of footswitch	
			Output power	± 15 %
			Return electrode monitor	
			Alarms	
			Complete model-specific performance testing	

 ©University of Vermont, Rev. 2 – Confidential

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage

Preventive maintenance

Replace filters: Inspect filters and replace as necessary. Refer to the device service manual for filter replacement.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

*****IMPORTANT*****

DO NOT TOUCH THE CABLES AND CONNECTORS FROM THE ACTIVE OR DISPERSIVE ELECTRODES WHILE THE ESU IS ACITVE. DO NOT ALLOW CABLES OR CONNECTORS TO COME IN CONTACT WITH CONDUCTIVE SURFACES SUCH AS METAL TABLES. DEACTIVATE THE ESU BEFORE ADJUSTING OR REMOVING CONNECTIONS.

ESU with handpiece connected to QA-ES II.

Performance inspection

Inspect dispersive electrode: Inspect reusable dispersive electrodes for cracks, bends, burn marks, severe scratching, or a build up of gel. Electrodes should be smooth and clean to allow the maximum contact area to the patient.

Operation of footswitch: Check the physical condition of the footswitch. Ensure the footswitch does not stick in the on position. Both cut and coagulation mode should be able to be activated from the footswitch.

Output power: Connect the monopolar active electrode of the ESU to the red 'VAR. LOAD' connector on the QA-ES II. Connect the dispersive electrode of the ESU to the black 'VAR. LOAD' connector on the QA-ES II.

Put the QA-ES II in continuous mode. From the main menu, press F2 'KNOB PARAM' until an asterisk (*) appears beside Mode. Turn the encoder knob until 'Cont. Oper' appears on the screen. Press F2 to adjust the test load. An asterisk should appear by Load on the screen. Use the encoder knob to select the load resistance. Check the ESU's service manual for the appropriate load resistance.

Press F3 'START" to start measuring the energy output. Put the ESU in cut mode and set the energy output to minimum. Activate the ESU and measure the energy output on the screen of the QA-ES II.

Adjust the ESU output to its maximum cut setting. Measure the output on the QA-ES II in **cut** mode according to the table below. The actual output should be within 15 % of the set output. For an output setting of 300 W, the measured output should be between 225 W and 345 W. Measure the output at 75 %, 50 %, and 25 % of the maximum setting.

Repeat the output measurements with the ESU in coagulation mode according to the table below. Start with the minimum setting and then outputs at 100 %, 75 %, and 25 % of the maximum setting. All measurements should be within 15 % of the set output.

	Power setting		Output (± 15 %)		Test results		
Test mode	% of max	Setting	Low	High	Reading	Pass	Fail
Cut	100 %	300 W	255 W	345 W			
	75 %	225 W	191.3 W	258.8 W			
	50 %	150 W	127.5 W	172.5 W			
	25 %	75 W	63.8 W	86.3 W			
Coagulation	100 %	120 W	102 W	138 W			
	75 %	90 W	76.5 W	103.5 W			
	50 %	60 W	51 W	69 W			
	25 %	30 W	25.5 W	34.5 W			

Remove the monopolar electrode from red 'VAR. LOAD' connector on the QA-ES II and the dispersive electrode from the black connector. Connect the ESU bipolar active electrode to the red 'VAR LOAD' connector. Connect the return of the bipolar electrode to the black 'VAR LOAD' connector. The dispersive cable will need to remain connected to the ESU to avoid activating the return electrode alarm. Be sure the dispersive electrode is placed on a non-conductive surface where the electrode will not come into contact with anyone. The load resistance may need to be adjusted for bipolar operation. Repeat the output measurements detailed above for both **cut and coagulation** modes according to the table below.

	Power setting		Output (± 15 %)		Test results		
Test mode	% of max	Setting	Low	High	Reading	Pass	Fail
Cut	100 %	50 W	42.5 W	57.5 W			
	75 %	37.5 W	31.9 W	43.1 W			
	50 %	25 W	21.3 W	28.8 W			
	25 %	12.5 W	10.6 W	14.4 W			
Coagulation	100 %	50 W	42.5 W	57.5 W			
	75 %	37.5 W	31.9 W	43.1 W			
	50 %	25 W	21.3 W	28.8 W			
	25 %	12.5 W	10.6 W	14.4 W			

Return electrode monitor: Connect the dispersive electrode to the ESU and connect the two wires of the dispersive electrode to the red and black 'VAR.LOAD' connectors of the QA-ES II. To make a quick test set from a disposable dispersive electrode, cut the electrode from the cable and separate the two wires in the dispersive cable. Strip the wires and attach banana plug connectors.

Press F2 'KNOB PARAM.' on the QA-ES II until the asterisk appears next to Mode. Use the encoder knob to select REM test and then press enter to select the test. Press F2 'KNOB PARAM' to select Delay. Turn the encoder knob to set the delay to 3000 ms.

Press F3 'START' on the QA-ES II. The load resistance will start at 10 Ω and gradually increase. Press F3 'STOP' to stop the test when the alarm sounds. The return electrode alarm should also sound if the dispersive cable is disconnected from the ESU. The ESU should not activate when the return electrode monitor is alarming.

Verify operation of alarms: Simulate any alarm conditions. Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any settings that were adjusted to their original settings.

Enteral feeding pump

Enteral feeding pumps are used in patients without gastrointestinal complications who are unable or unwilling to consume adequate nutrients. Feeding solutions are delivered to the patient through temporary or surgically implanted feeding tubes. The pumps accurately control the flow of liquid feeding solutions that are administered enterally, through the digestive tract. These pumps will utilize a pump mechanism such as a rotary peristaltic pump, linear peristaltic pump, or a volumetric pump. Most pumps record the dose rate, dose settings, and infused volume in the memory. Audible and visual alarms alert the user to flow changes or malfunctions.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	4
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	1
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	1
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		10
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

Enteral feeding pump procedure

Estimated time: 20 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
IDA 4 Plus Infusion Device Analyzer (or equivalent)
Tubing set for feeding pump
Reservoir to connect to tubing set (bag or bottle)
20 cc or larger syringe
3 way stopcock
Tubing and connectors to connect to IDA 4 Plus

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Clean flow detector	
			Replace battery every 24 months	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify unit operates on battery	
			Pole clamp function	
			Flow rate accuracy	± 10 %
			Volume accuracy	± 10 %
			Occlusion detection pressure	± 1 psi
			Alarm function	
			Complete model-specific performance testing	

 ©University of Vermont, Rev. 2 – Confidential

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage.

Preventive maintenance

Clean flow detector: Inspect the flow detector on the feeding pump. Clean any debris from the flow sensor.

Replace battery: The battery should be replaced every 24 months. Replace if necessary.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Verify unit operates on battery: Check that the ac power indicator is lit when the power cord is plugged into an outlet. Unplug the ac power cord and perform the remainder of the functional test on battery power. The ac power indicator should go out when the power cord is unplugged and the battery indicator should light. Be sure to plug the power cord in at the conclusion of the test.

Pole clamp function: Check the physical condition of the pole clamp. The pole clamp should be securely fastened to the feeding pump. The clamp mechanism should move freely. The pole clamp should secure the feeding pump to the IV pole.

Flow rate accuracy: Fill the infusion reservoir with a 1 % detergent solution in de-ionized water. Prepare a 1 % stock solution of detergent such as Cole-Parmer Micro-90 in volume using de-ionized water. The solution may be stored in a closed vessel for up to 6 months. This solution should then be diluted 10:1 with de-ionized water for daily use. If the water used causes too much foaming, a 20:1 dilution is recommended. Do not use tap water or solutions intended for patient use, as these may harm the transducers in the IDA 4 Plus.

Connect the feeding tubing to the reservoir. Prime the set so there is no air in the tubing. With the tubing draining into a container or sink, open the flow control mechanism on the tubing set. Hold the reservoir high enough above the tubing so that fluid flows through the tubing under the force of gravity. Allow fluid to flow through the tubing until no air bubbles can be seen in the tubing. Insert the set into the feeding pump. Connect the three-way stopcock to the channel 1 port on the IDA4 Plus. Connect the patient feeding tubing to one port of the stopcock. Fill the syringe with the detergent solution and connect this to the other port of the stopcock. Connect a piece of tubing to the drain port of channel 1 and run the tubing into a container to catch the used solution.

From the main menu of the IDA 4 Plus, use the arrow keys to highlight 'SETUP' under channel 1 and then press 'ENT'. Use the arrow keys to highlight 'FLOW' and press 'ENT'. Select 'PRIME'. Close the stopcock port connected to the feeding tubing, leaving the ports to the syringe and the IDA 4 Plus open. Inject the solution in the syringe into the IDA 4 Plus until 'START' appears on the screen. Select 'AutoSTART'. The IDA 4 Plus will start the flow test when it detects flow from the pump. Close the port to the syringe, leaving the ports to the tubing and the IDA 4 Plus open.

Set the flow rate on the feeding pump to 60 mL/hr and set the dose to 10 mL. Start the feeding pump. When the pump alarms complete, select 'END' on the IDA 4 Plus to end the test. At this rate and volume, the dose should be complete in approximately 10 minutes. Clear the alarm on the pump. The measured flow rate should be within 10 % of the set rate. For a flow rate of 60 mL/hr, the flow rate should be between 54 mL/hr and 66 mL/hr. Set the flow rate on the pump to 120 mL/hr and the dose to 10 mL. Repeat the flow test at the higher flow rate.

The IDA 4 Plus is equipped with four channels to analyze infusion devices. Four pumps can be run simultaneously.

Volume accuracy: Set up the feeding pump and the IDA 4 Plus as described previously in Flow Rate Accuracy. The IDA 4 Plus will measure flow rate and volume simultaneously. The delivered volume should be within 10 % of the set volume. For a set volume of 10 mL, the measured volume should be within 9 mL and 11 mL.

Occlusion detection pressure: From the channel set up menu on the IDA 4 Plus, select 'OCCLUSION'. Prime the IDA 4 Plus with the syringe if necessary. Set the flow rate on the feeding pump to 100 mL/hr. Set the volume to 10 mL or more so that the volume will not be delivered before the test is complete. Start the pump. Select 'START' on the IDA 4 Plus. Select 'END' on the IDA 4 Plus when the pump alarms occlusion. Note the pressure at which the pump alarms. Compare the measured pressure to the occlusion pressure of the pump. The occlusion pressure will be specific to the model. Check the service manual for the specific pressure. The measured occlusion pressure should be within 1 psi of the pump's occlusion pressure. For an occlusion pressure of 20 psi, the measured pressure should be between 19 psi and 21 psi.

Alarm function: Check that all alarms are functional and that the volume is adequately loud. Ensure appropriate visual indicators are functioning.

Set the rate on the pump to 100 mL/hr and set the volume to 100 mL. Start the pump. Occlude the tubing between the reservoir and the pump. The tubing can be occluded either by closing a clamp attached to the tubing or by pinching the tubing with a set of hemostats or pliers. The pump should alarm upstream occlusion.

Clear the alarm and restart the pump. Occlude the tubing after the pump. The pump should alarm downstream occlusion. Clear the alarm.

If the pump is equipped with an air detector introduce air into the tubing. This can be done by turning the reservoir upside down until a bubble of air is pulled through the tubing. Turn the reservoir right side up. When the air bubble gets to the pump, the pump should alarm air in line. Clear the alarm. Remove the tubing from the pump and prime the set so that there is no air in the tubing. Reinsert the tubing set into the pump and restart the pump.

Simulate an empty container situation either by turning the reservoir upside down so that no fluid can get to the tubing, or by removing the tubing from the reservoir. The pump should alarm when no fluid flow is detected.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any settings that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions. Plug in the power cord to ensure the battery remains charged.

External pacemaker

External pacemakers electric impulse to the heart through the chest wall in order to temporary pacing of the heart. External pacemakers consist of electronic circuitry that controls the pulse rate and output current and a two lead cable used to connect it to disposable adhesive electrodes. Electrical impulses are delivered to the heart, causing the heart to contract. All chambers of the heart are stimulated simultaneously. External pacemakers are used to assist in resuscitation, correct arrhythmias such as asystole or bradycardia, or to temporarily pace during procedures that may induce these arrhythmias.

Recommended functional test frequency: semiannual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	
Device is used for a life support	5	5
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	
Device failure could result in severe injury to, or death of, patient or user	4	4
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	
A significant history of incidents exists	2	2
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		14
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		2

External non-invasive pacemaker procedure

Estimated time: 20 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
SigmaPace 1000 External Pacemaker Analyzer (or equivalent)
Cables and connectors to connect pacemaker to analyzer

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Replace battery every 24 months	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify unit operates on battery	
			Rate accuracy	± 5 %
			Output accuracy	± 10 %
			Pulse width	± 10 %
			Alarm function	
			Complete model-specific performance testing	

 ©University of Vermont, Rev. 2 – Confidential

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance, chassis leakage, and lead leakage.

Preventive maintenance

Replace battery: The battery should be replaced every 24 months. Replace if necessary.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Verify unit operates on battery: Check that the ac power indicator is lit when the power cord is plugged into an outlet. Unplug the ac power cord and perform the remainder of the functional test on battery power. The ac power indicator should go out when the power cord is unplugged and the battery indicator should light. Be sure to plug the power cord in at the conclusion of the test.

Output accuracy: Connect the pacemaker to the input jacks on the front of the analyzer. Power on the analyzer and press F1, 'NONINV', to select non-invasive pacing. Press F3, 'BRAND' to cycle through the available manufacturers. The preset test load will appear for each manufacturer. If necessary, press F4, LOAD', to adjust the test load. Refer to the pacemaker's manual for the proper load. Press F1, 'NEXT', once the proper manufacturer and test load have been selected.

Set the pacing rate on the pacemaker to 80 ppm. Set the pacemaker output to the minimum setting and start pacing. The SigmaPace 1000 will display the pacer output amplitude in mA. Measure the pacer output over its entire range. The measured output should be within 10 % of the set output. For an output setting of 100 mA, the measured output should be between 90 mA and 110 mA.

*****IMPORTANT*****

DO NOT TOUCH EXPOSED CONNECTORS WHILE THE PACEMAKER IS ON. TURN THE PACER OFF BEFORE ADJUSTING OR REMOVING CONNECTIONS.

Rate accuracy: While measuring pacer output, the SigmaPace 1000 also displays the pulse rate. The measured pulse rate should be within 5 % of the set rate. For a rate of 80 ppm, the pulse rate should be between 84 ppm and 76 ppm. Slowly adjust the pulse rate on the pacemaker and measure the pulse rate throughout its range.

Pulse width: While measuring pacer output, the SigmaPace 1000 will display the pulse width. Typical pulse widths are between 0.5 mSec to 2.0 mSec. Measure the pulse width across its range. The measured pulse width should be within 10 % of the set width. For a pulse width of 2.0 mSec, the measured pulse width should be between 1.8 mSec and 2.2 mSec.

Verify operation of alarms: Simulate any alarm conditions. Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

Complete model-specific performance testing: Refer to the electrosurgical unit's service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any settings that were adjusted to their original settings. If equipped with a power cord or charger, plug in to ensure the battery remains charged and ready for use.

Fetal monitor

Fetal monitors measure fetal heart rate and maternal uterine contractions during labor to assess the progress of labor and the health of the mother and fetus. Fetal monitors may use non-invasive or invasive methods for monitoring. For non-invasive monitoring, measurements are taken from transducers placed on the mother's abdomen. An ultrasound transducer is used to measure the fetal heart rate. Uterine contractions are measured using a tocodynamometer transducer. During invasive monitoring, electrodes are placed on the scalp or other exposed skin of the fetus to measure the fetal heart rate. Intrauterine pressure is measured directly through a pressure transducer located on a catheter that is inserted into the uterus. Fetal monitors may have additional monitoring capabilities, such as maternal heart rate and blood pressure.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	3
Device is used to deliver direct treatment to the patient	4	
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	3
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant History	1	1
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		10
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

 ©University of Vermont, Rev. 2 – Confidential

FLUKE®
Biomedical

Fetal monitor procedure

Estimated time: 30 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
PS320 Fetal Simulator (or equivalent)
MFH–1 Mechanical Fetal Heart (or equivalent)
Cables to connect fetal monitor to analyzer
Stopwatch or clock with second hand
Ultrasound gel

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Replace battery every 24 months	
			Clean rollers and paper guides	
			Lubricate motor and paper drive mechanism	
			Verify proper time and date, correct if necessary	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify unit operates on battery	
			Fetal heart rate accuracy	± 5 %
			Maternal heart rate accuracy	± 5 %
			Intrauterine pressure accuracy	± 2 %
			Recorder speed (3 cm/min)	± 4 %
			Alarm function	
			Complete model-specific performance testing	

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance, chassis leakage, and lead leakage.

Preventive maintenance

Replace battery: The battery should be replaced every 24 months. Replace if necessary.

Clean rollers and paper guides: Inspect the rollers and paper guides and remove any debris. Check for bits of torn paper caught in the rollers.

Lubricate motor and paper drive mechanism: Follow the manufacturer's instructions in the service manual for lubricating the motor and paper drive mechanism. Not all motors will need to be lubricated.

Verify proper time and date, correct if necessary: Verify the time and date displayed on the monitor is correct. If the time and date is not displayed on the monitor, print a strip from the recorder. The time and date should appear on the printed strip. Correct the time and date as necessary.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Verify unit operates on battery: Check that the ac power indicator is lit when the power cord is plugged into an outlet. Unplug the ac power cord and perform the remainder of the functional test on battery power. The ac power indicator should go out when the power cord is unplugged and the battery indicator should light. Be sure to plug the power cord in at the conclusion of the test.

Fetal heart rate accuracy: If the fetal monitor uses fetal scalp electrodes, connect the ECG cable to the connectors on the side of the PS320. Use the fetal up and down buttons to set a fetal heart rate of 120 bpm. The displayed heart rate should be within 5 % of the set rate. For a simulated heart rate of 120 bpm, the displayed rate should be between 114 bps and 126 bps.

Connect the ultrasound cable from the ultrasound connector on the fetal monitor to the US1 port of the PS320. If the fetal monitor is equipped with two ultrasound inputs, connect a second ultrasound cable to the US2 port of the analyzer. As above, the displayed heart

Testing ultrasound transducers with the MFH-1 Fetal Heart Simulator.

 ©University of Vermont, Rev. 2 – Confidential

rate should be within 5 % of the set rate. For a simulated heart rate of 120 bpm, the displayed rate should be between 114 bps and 126 bps. Disconnect the cables from the PS320 analyzer.

To test the operation of the ultrasound transducers, connect the MFH-1 Fetal Heart Simulator to the US1 port of the PS320 analyzer. The analyzer will need to be used with the battery eliminator, as the MFH-1 cannot run on battery power. Connect an ultrasound transducer to the fetal monitor. Place the transducer face up on a flat surface and coat with ultrasound gel. Place the MFH-1 on top of the transducer with the simulation window facing the transducer. The fetal heart rate will be displayed on the monitor and should be within 5 % of the set rate. For a simulated heart rate of 120 bpm, the displayed rate should be between 114 bpm and 126 bpm. Repeat this process for each ultrasound transducer. Remove the MFH-1 from the PS320.

Maternal heart rate accuracy: Connect the ECG cable to the connectors on the side of the PS320. Use the maternal up and down buttons to set a maternal heart rate of 60 bpm. The displayed heart rate should be within 5 % of the set rate. For a simulated heart rate of 60 bpm, the displayed rate should be between 57 bpm and 63 bpm.

Intrauterine pressure accuracy: Connect the TOCO cable from the TOCO connector on the fetal monitor to the TOCO port of the PS320. Use the TOCO button to scroll through the available settings. The displayed intrauterine pressure should be within 2 % of the set pressure. For a simulated pressure of 50 mm, the displayed pressure should be between 49 mm and 51 mm.

Recorder speed: Record a strip on the fetal monitor. Use the mark function on the recorder to place a mark on the paper. Use a stopwatch or clock to time 150 seconds (2.5 minutes). Place another mark on the paper. Measure the distance between the marks. With a recorder speed of 3 cm/min, the marks should be between 72 mm and 78 mm.

Verify operation of alarms: Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

Note the alarm settings on the monitor. Adjust the fetal heart rate on the PS320 down to just below the monitor's low heart rate limit. The alarm should sound. Increase the fetal heart rate above the low alarm point. Clear the alarm if necessary. Increase the fetal heart rate to just above the high heart rate limit. Note that the alarm sounds when the heart rate increases beyond the high alarm limit. Set the fetal heart rate back to 120 bpm and clear any alarms. Repeat the process for the maternal heart rate alarm.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any alarms that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions. Clean ultrasound gel from the transducers. Plug in the power cord to ensure the battery remains charged.

Hypo/hyperthermia unit

Hypo/hyperthermia units regulate a patient's temperature using circulating water. By adjusting the temperature of the water, the patient may be either heated or cooled. These devices typically consist of a water reservoir, a heating element, a cooling system, a pump for circulating water, and a blanket designed for water circulation. The units will also have a thermostat and circuitry for maintaining a set temperature.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	4
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	3
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	1
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		11
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

 ©University of Vermont, Rev. 2 – Confidential

FLUKE®
Biomedical

Hypo/hyperthermia unit procedure

Estimated time: 35 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
DPM 4 with temperature probe (or equivalent)
Water flow meter
Tubing and connectors to connect flow meter

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Inspect and clean reservoir	
			Lubricate motor	
			Complete model-specific preventive maintenance	
Performance testing				
			Fluid level	
			Flow rate	
			Temperature accuracy	± 1 °C
			High temperature protection	≥ 43 °C
			Low temperature protection	≤ 1 °C
			Temperature probe accuracy	± 1 °C
			Alarms	
			Complete model-specific performance testing	

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage.

Preventive maintenance

Inspect and clean reservoir: Empty the water reservoir. Check for cracks and leaks. Inspect the condition of rubber seals and replace as necessary. Clean any debris or mineral build up from the reservoir. Refill the reservoir tank with distilled water. Do not fill with tap water, as this may cause mineral build up in the device.

Lubricate motor: Follow the manufacturer's instructions in the service manual for lubricating the pump motor. Not all motors will need to be lubricated.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Fluid level: Ensure there is an adequate water level in the reservoir. There should be sufficient water for circulating throughout the blanket, but the water reservoir should not be overfilled.

Flow rate: Connect a blanket to the hypo/hyperthermia unit. Connect a water flow meter between the outlet of the hypo/hyperthermia unit and the inlet of the blanket. Check the service manual for flow rate specifications.

Temperature accuracy: Connect the temperature probe to the Temp connector on the side of the DPM 4. If the temperature units need to be changed, press the soft key labeled 'UNIT' on the DPM 4 and then use the menu scroll keys until 'C/F' is displayed. Press the soft key labeled 'C/F' to toggle between the Celsius and Fahrenheit scales.

Connect a blanket to the hypo/hyperthermia unit. Insert the temperature probe into the water reservoir to measure the temperature of the circulating water. Set the temperature of the hypo/hyperthermia unit to its lowest setting. Allow the water temperature to stabilize. Repeat the temperature measurement with a midrange temperature and the maximum temperature setting. The measured temperature should be within 1 °C of the set temperature. For a set temperature of 42 °C, the measured temperature should be between 41 °C and 43 °C.

Testing water temperature with the DPM 4.

 ©University of Vermont, Rev. 2 – Confidential

High temperature protection: Connect a blanket to the hypo/hyperthermia unit and insert the temperature probe into the water reservoir. Set the temperature on the hypo/hyperthermia unit to its maximum setting.

If the hypo/hyperthermia unit is equipped with a patient temperature probe, expose the temperature probe to room air. The temperature of the circulating water should increase until the hypo/hyperthermia unit alarms temperature. Note the temperature at which the alarm sounds on the DPM 4. Check the service manual for the specific high temperature limit and compare this value with the measured temperature. The measured temperature should be within 1 °C of the high temperature limit. For a high temperature limit of 44 °C, the measured high temperature should be between 43 °C and 45 °C.

If the hypo/hyperthermia is not equipped with a patient temperature probe, follow the manufacturer's procedure for overriding the thermostat.

Low temperature protection: If the hypo/hyperthermia unit is equipped with a low temperature alarm, set the temperature on the hypo/hyperthermia unit to its lowest setting.

If the hypo/hyperthermia unit is equipped with a patient temperature probe, expose the temperature probe to room air. The temperature of the circulating water should decrease until the hypo/hyperthermia unit alarms low temperature. Note the temperature at which the alarm sounds on the DPM 4. Check the service manual for the specific low temperature limit and compare this value with the measured temperature. The measured temperature should be within 1 °C of the low temperature limit.

If the hypo/hyperthermia is not equipped with a patient temperature probe, follow the manufacturer's procedure for overriding the thermostat.

Temperature probe accuracy: Fill a container with warm water at about 30 °C. Insert the temperature probe from the hypo/hyperthermia unit and the temperature probe from the DPM 4 into the water. The temperature displayed on the hypo/hyperthermia unit should be within 1 °C of the temperature measured on the DPM 4. For a temperature of 30 °C, the displayed temperature should be between 29 °C and 31 °C.

Alarm function: Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

If the hypo/hyperthermia unit is equipped with a low reservoir alarm, drain the reservoir to below the low water level. Run the hypo/hyperthermia unit. The low reservoir alarm should sound. Fill the reservoir with distilled water until the alarm clears.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any settings that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions. If the hypo/hyperthermia unit is going to be used in the near future, Ensure there is an adequate water level in the reservoir. If the hypo/hyperthermia unit will not be used soon, drain the water from the reservoir.

Infant incubator

Infant incubators provide a closed controlled environment to maintain appropriate temperature, humidity, and oxygen levels for infants and are used mainly for premature infants and other newborns that cannot regulate their body temperature by themselves. Infant incubators typically consist of a clear removable plastic hood with a mattress, a heater, a fan for circulating warm air, and temperature controls. Temperature sensors may measure air temperature inside the incubator, the infant's body temperature through a skin probe, or both. Most incubators also include humidity controls and a means for adjusting oxygen levels.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	4
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	
Device failure could result in severe injury to, or death of, patient or user	4	4
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	1
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		12
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

 ©University of Vermont, Rev. 2 – Confidential

FLUKE®
Biomedical

Infant incubator procedure

Estimated time: 120 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
INCU incubator analyzer (or equivalent)
Stopwatch or watch with a second hand
Heat Gun

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Clean cooling vents and filters	
			Inspect and clean ducts, heater, and fans	
			Inspect gaskets for signs of deterioration	
			Inspect port closures and port sleeves	
			Replace battery every 24 months	
			Complete model-specific preventive maintenance	

continued on page 90

Infant incubator procedure

Estimated time: 120 minutes

continued from page 89

Test Result				
Pass	**Fail**	**N/A**		
Performance testing				
			Verify unit operates on battery	
			Fan operation	
			Warm up time	± 20 %
			Air temperature accuracy	± 1 ºC
			Skin temperature accuracy	± 0.3 ºC
			Temperature overshoot	± 2 ºC
			Relative humidity	± 10 %
			Air flow	≤ 0.35 m/s
			Air temperature alarms	
			Skin temperature alarms	
			High temperature protection	≤ 40 ºC
			Noise level	≤ 60 dB normal conditions ≤ 80 dB alarm activated ≥ 80 dB alarm activated, 3 m from incubator
			Alarm function	
			Complete model-specific performance testing	

 ©University of Vermont, Rev. 2 – Confidential

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

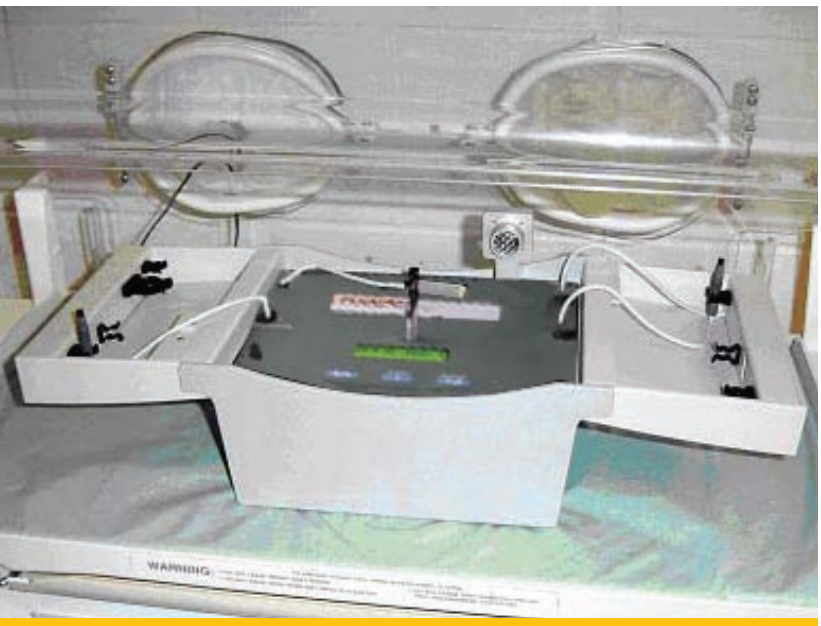
Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage.

Preventive maintenance

Clean cooling vents and filters: Inspect vents and air filters. Use a portable vacuum to clean dust from air ducts. Clean or replace filters as necessary. Ensure that filters are installed properly.

Inspect gaskets for signs of deterioration: Check rubber or plastic gaskets and seals for signs of deterioration. Replace as necessary.

Inspect port closures and port sleeves: Inspect port doors and iris seals for proper closure. Inspect the port gloves for holes or other signs of wear.



INCU inside incubator.

Replace battery: The battery should be replaced every 24 months. Replace if necessary.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Verify unit operates on battery: Check that the ac power indicator is lit when the power cord is plugged into an outlet. Unplug the ac power cord and perform the remainder of the functional test on battery power. The ac power indicator should go out when the power cord is unplugged and the battery indicator should light. Be sure to plug the power cord in at the conclusion of the test.

Fan operation: Inspect the fan blades for damage. Look for chips, warping, melting, and missing blades. Ensure there is adequate clearance around the fan assembly. Look for signs of rubbing around the fan housing. Lubricate the fan motor per the manufacturer's specification. Follow the manufacturer's instructions in the service manual for lubricating the pump motor. Not all motors will need to be lubricated.

Warm-up time: With the incubator at room temperature, set the incubator temperature for 12 °C above ambient temperature (typically 36 °C). Use a stopwatch to time how long it takes for the temperature to stabilize. The measured warm-up time should be within 20 % of the manufacturer's specified warm-up time. For a warm-up time of 30 minutes, the measured warm up time should be within 24 minutes and 36 minutes.

Air temperature accuracy: Set the incubator temperature to 32 °C. Place the INCU in the center of the incubator. Place the T1 and T3 temperature probes so that they are placed vertically in opposite corners. Place the T2 probe in the center holder. Attach the air flow sensor and rotate the sensor so that it is perpendicular to the air flow within the incubator. If the incubator is equipped with a skin temperature probe, place the skin probe in close proximity to the T2 sensor. Allow the incubator temperature to stabilize. Press the 'SELECT' button on the INCU to cycle through the readings. The measured air temperature should be within 1 °C of the set temperature. For a set temperature of 32 °C the measured temperature should be between 31 °C and 33 °C.

Set the temperature on the incubator to 36 °C and allow the temperature to stabilize. Repeat the temperature measurements at 36 °C.

Skin temperature accuracy: Place the skin temperature probe in close proximity to the T2 sensor on the INCU. Allow the incubator temperature to stabilize. The measured temperature on the T2 sensor should be within 0.3 °C of the displayed skin temperature on the incubator. For a displayed skin temperature of 36.0 °C, the measured temperature should be between 35.7 °C and 36.3 °C.

Temperature overshoot: From a stabilized incubator temperature of 32 °C, increase the incubator temperature to 36 °C. Allow the temperature to stabilize. During temperature stabilization, the temperature in the incubator should not overshoot the set temperature by more than 2 °C. For a set temperature of 36 °C, the incubator temperature should not exceed 38 °C during temperature stabilization.

Relative humidity: If the incubator is equipped with a display for relative humidity, note the relative humidity measured on the INCU. The measured relative humidity should be within 10 % of the displayed relative humidity. For a displayed relative humidity of 50 %, the measured relative humidity should be between 45 % and 55 %.

Air flow: With the INCU placed in the center of the incubator, rotate the air flow sensor so that it is perpendicular with the airflow in the incubator. Note the air velocity measurement on the INCU. The air velocity should not exceed 0.35 m/s.

Air temperature alarms: Set the incubator temperature to 36 °C and allow the temperature to stabilize. Open the incubator hood to room air. Verify that the low temperature alarm sounds. Close the incubator and allow the temperature to stabilize at 36 °C. Use a heat gun to increase the air temperature. Note the temperature at which the alarm sounds.

*****CAUTION*****

DO NOT USE THE AIR FLOW SENSOR IN THE PRESENCE OF OXYGEN. THE SENSOR USES A HOT-WIRE TECHNIQUE FOR AIR VELOCITY MEASUREMENT AND MAY BECOME A SOURCE OF IGNITION.

Placement of air flow sensor.

 ©University of Vermont, Rev. 2 – Confidential

Skin temperature alarms: Adjust the skin temperature set point on the incubator to 36 °C. Place the sensor in the incubator and allow the temperature to stabilize. Remove the skin temperature sensor from the incubator and verify that the low temperature alarm sounds. Place the skin temperature sensor in a cup of warm water. Ensure the water is warm enough to activate the high temperature alarm.

High temperature protection: Set the incubator temperature to its maximum setting and allow the temperature to stabilize. Use a heat gun to blow hot air into the incubator to raise the temperature above the maximum setting. Note the temperature at which the over temperature alarm activates.

Noise level: With the incubator running and the INCU placed in the center of the incubator, measure the sound level inside the incubator. Press the 'SELECT' button on the INCU to cycle through the measurements until the sound level is displayed. All ports and doors should be closed for this measurement. The sound level within the incubator should not exceed 60 dB. The most common cause of high sound levels in the incubator is a noisy fan assembly. Activate an alarm. The sound level in the incubator with the alarm sounding should not exceed 80 dB.

Remove the INCU from the incubator and place it 3 m from the front of the incubator. Activate an alarm on the incubator and measure the sound level with the INCU. The alarm should be at least 80 dB at this distance.

Alarm function: Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

Unplug the temperature probe from the incubator. The disconnected probe alarm should activate. If the incubator is equipped with alarms for an open or short circuited temperature probe, use open and short circuited probe plugs to test these alarms. Disconnect the skin temperature probe and connect the probe plugs. The appropriate alarms should activate.

Unplug the incubator to simulate a power failure. The power failure alarm should activate.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any settings that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions. Plug in the power cord to ensure the battery remains charged.

Infusion pump

Infusion pumps deliver controlled and accurate infusion of liquids to a patient through intravenous, epidural, or subcutaneous routes. These pumps may utilize a peristaltic pump mechanism, a volumetric pump mechanism that repeatedly compresses a specific amount of fluid into a cassette, or a syringe driven mechanism for propelling the infusate. Adjustable settings control the flow rate and volume to be infused. Audible and visual alarms alert the user to flow changes or malfunctions. Most infusion pumps include a memory function that records does settings and alarms.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	4
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	3
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	
A significant history of incidents exists	2	2
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		12
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

FLUKE®
Biomedical

Infusion pump procedure

Estimated time: 45 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
IDA 4 Plus Infusion Device Analyzer (or equivalent)
Reservoir to connect to tubing set (bag or bottle)
Tubing and connectors to connect to IDA 4 Plus
Tubing set for infusion pump
20 cc or larger syringe
3 way stopcock

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Clean flow detector	
			Replace battery every 24 months	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify unit operates on battery	
			Pole clamp function	
			Flow rate accuracy	± 10 %
			Volume accuracy	± 10 %
			Infusion complete/KVO	
			Occlusion detection pressure	± 1 psi
			Piggyback infusion	
			Alarm function	
			Complete model-specific performance testing	

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage.

Preventive maintenance

Clean flow detector: Inspect the flow detector on the infusion pump. Clean any debris from the flow sensor.

Replace battery: The battery should be replaced every 24 months. Replace if necessary.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Verify unit operates on battery: Check that the ac power indicator is lit when the power cord is plugged into an outlet. Unplug the ac power cord and perform the remainder of the functional test on battery power. The ac power indicator should go out when the power cord is unplugged and the battery indicator should light. Be sure to plug the power cord in at the conclusion of the test.

Pole clamp function: Check the physical condition of the pole clamp. The pole clamp should be securely fastened to the infusion pump. The clamp mechanism should move freely. The pole clamp should secure the infusion pump to the IV pole.

Flow rate accuracy: Fill the infusion reservoir with a 1 % detergent solution in de-ionized water. A 1 % stock solution of detergent such as Cole-Parmer Micro-90 should be prepared in volume using de-ionized water; this may be stored in a closed vessel for up to 6 months. The solution should then be diluted 10:1 with de-ionized water for daily use. If the water used causes too much foaming, a 20:1 dilution is recommended. Do not use tap water or solutions intended for patient use, as these may harm the transducers in the IDA 4 Plus.

Connect the infusion tubing to the reservoir. Prime the set so that there is no air in the tubing. With the tubing draining into a container or sink, open the flow control mechanism on the tubing set. Hold the reservoir high enough above the tubing so that fluid flows through the tubing under the force of gravity. Allow fluid to flow through the tubing until no air bubbles can be seen in the tubing. Insert the set into the infusion pump. Connect the three-way stopcock to the channel 1 port on the IDA 4 Plus. Connect the patient infusion tubing to one port of the stopcock. Fill the syringe with the detergent solution and connect this to the other port of the stopcock. Connect a piece of tubing to the drain port of channel 1 and run the tubing into a container to catch the used solution.

Infusion pump connected to the IDA 4 Plus.

 ©University of Vermont, Rev. 2 – Confidential

From the main menu of the IDA 4 Plus, use the arrow keys to highlight 'SETUP' under channel 1 and then press 'ENT'. Use the arrow keys to highlight 'FLOW' and press 'ENT'. Select 'PRIME'. Close the stopcock port connected to the infusion tubing, leaving the ports to the syringe and the IDA 4 Plus open. Inject the solution in the syringe into the IDA 4 Plus until 'START' appears on the screen. Select 'Auto-START'. The IDA 4 Plus will start the flow test when it detects flow from the pump. Close the port to the syringe, leaving the ports to the tubing and the IDA 4 Plus open.

Set the flow rate on the infusion pump to 60 mL/hr and set the dose to 10 mL. Start the infusion pump. When the pump alarms complete, select 'END' on the IDA 4 Plus to end the test. At the set rate and volume, the dose should be complete in approximately 10 minutes. Clear the alarm on the pump. The measured flow rate should be within 10 % of the set rate. For a flow rate of 60 mL/hr, the flow rate should be between 54 mL/hr and 66 mL/hr. Set the flow rate on the pump to 120 mL/hr and the dose to 10 mL. Repeat the flow test at the higher flow rate.

The IDA 4 Plus is equipped with four channels to analyze infusion devices. Four pumps can be run simultaneously.

Volume accuracy: Set up the infusion pump and the IDA 4 Plus as described previously in Flow Rate Accuracy. The IDA 4 Plus will measure flow rate and volume simultaneously. The delivered volume should be within 10 % of the set volume. For a set volume of 10 mL, the measured volume should be within 9 mL and 11 mL.

Infusion complete/KVO: At the conclusion of an infusion, the infusion pump should alarm 'infusion complete' or 'KVO'. If the pump alarms 'KVO' it is supplying a very low flow rate in order to keep the vein open if another infusion needs to be given. Measure the KVO rate using the 'FLOW' function on the IDA 4 Plus.

Set up the infusion pump with a high flow rate and low volume, such as 300 mL/hr and 2 mL. Start the pump and allow the infusion to complete. When the infusion is complete, do not stop the pump, instead silence the alarm and let the pump run. Enter the 'FLOW' screen on the IDA 4 Plus to measure the KVO rate. Several minutes may be required for the analyzer to be able to measure the low rate. The measured rate should be within 10 % of the infusion pump's KVO rate. For a KVO rate of 1 mL/hr, the measured rate should be between 0.9 mL/hr and 1.1 mL/hr.

Occlusion detection pressure: From the channel set up menu on the IDA 4 Plus, select 'OCCLUSION'. Prime the IDA 4 Plus with the syringe if necessary. Set the flow rate on the infusion pump to 100 mL/hr. Set the volume to 10 mL or more so that the volume will not be delivered before the test is complete. Start the pump. Select 'START' on the IDA 4 Plus. Select 'END' on the IDA 4 Plus when the pump alarms occlusion. Note the pressure at which the pump alarms. Compare the measured pressure to the occlusion pressure of the pump. The occlusion pressure will be specific to the model. Check the service manual for the specific pressure. The measured occlusion pressure should be within 1 psi of the pump's occlusion pressure. For an occlusion pressure of 20 psi, the measured pressure should be between 19 psi and 21 psi.

Piggyback infusion: From the channel set up menu on the ID A4 Plus, select 'DUAL FLOW'. Prime the IDA 4 Plus with the syringe if necessary. Use the arrow keys to enter the flow rates and volumes to be tested. Enter 60 mL/hr for the secondary rate, 10 mL for the secondary volume, 12 0mL/hr for the primary rate, and 10 mL for the primary volume. Select 'AutoSTART" to start the flow measurements when flow is first detected.

On the infusion pump, set the primary rate for 120 mL/hr and the primary volume to 10 mL. Set the piggyback flow rate to 60 mL/hr and the piggyback volume to 10 mL. Start the piggyback infusion.

The IDA 4 Plus will display the rate and volume for the piggyback infusion as 'FLOW 1'. When the piggyback infusion is completed, the infusion pump should automatically switch over to the primary infusion, and will usually sound an audible tone. The rate and volume for the primary infusion is displayed on the IDA 4 Plus as 'FLOW 2'. The delivered flow rates and volumes should be within 10 % of their set rates.

Alarm function: Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

Set the rate on the pump to 100 mL/hr and set the volume to 100 mL. Start the pump. Occlude the tubing between the reservoir and the pump. The tubing can be occluded either by closing a clamp attached to the tubing or by pinching the tubing with a set of hemostats or pliers. The pump should alarm upstream occlusion.

Clear the alarm and restart the pump. Occlude the tubing downstream from the pump. The pump should alarm downstream occlusion. Clear the alarm.

If the pump is equipped with an air detector, introduce air into the tubing. Turn the reservoir upside down until a bubble of air is pulled through the tubing. Turn the reservoir right side up. When the air bubble gets to the pump, the pump should alarm air in line. Clear the alarm. Remove the tubing from the pump and prime the set so that there is no air in the tubing. Reinsert the tubing set into the pump and restart the pump.

Simulate an empty container situation either by turning the reservoir upside down so that no fluid can get to the tubing, or by removing the tubing from the reservoir. The pump should alarm when no fluid flow is detected.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any settings that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions. Plug in the power cord to ensure the battery remains charged.

Non-invasive blood pressure monitor

A non-invasive blood pressure (NIBP) monitor measures and displays blood pressure using external sensors. These devices consist of an inflatable cuff, hose, pressure sensors, processor, and a display. Typically, NIBP monitors use an oscillometric method to measure blood pressure. The cuff is attached to a patient's arm and then inflated until blood flow is stopped. As the cuff is deflated, transducers measure pressure fluctuations. The monitor then processes the information from the pressure transducers and displays the systolic, diastolic, and mean pressure, typically in mmHg (millimeters of mercury). Most NIBP monitors will also display heart rate.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	3
Device is used to deliver direct treatment to the patient	4	
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	3
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	1
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		10
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

Non-invasive blood pressure monitor procedure

Estimated time: 25 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent) BP Pump2 NIBP Analyzer (or equivalent)
Stopwatch or watch with a second hand PVC pipe to attach tourniquet cuff to
Tubing and connectors to connect to DPM 4

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC, < 500 µA SFC
			Patient leakage current	< 100 µA B and BF, < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF, < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Check condition of tubing, cuffs, and hoses	
			Clean recorder paper compartment, rollers and paper guides	
			Lubricate motor and paper drive mechanism	
			Verify proper time and date, correct if necessary	
			Replace battery every 24 months	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify unit operates on battery	
			Leak test	≤ 15 mmHg/min
			Static pressure accuracy	± 3 mmHg
			Pressure relief test	≤ 330 mmHg
			Dynamic pressure accuracy	± 10 mmHg
			Heart rate accuracy	± 5 %
			Auto interval time	± 10 %
			Stop/Cancel/Deflate	≤ 10 sec
			Recorder operation	
			Alarm function	
			Complete model-specific performance testing	

 ©University of Vermont, Rev. 2 – Confidential

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage.

Preventive maintenance

Check condition of tubing, cuffs, and hoses: Inspect hoses and cuffs for signs of wear. Look for holes, cracks, and dry rot. Ensure that all connections are secure.

Clean recorder paper compartment, rollers, and paper guides: Inspect the rollers and paper guides and remove any debris. Check for bits of torn paper caught in the rollers.

Lubricate motor and paper drive mechanism: Follow the manufacturer's instructions in the service manual for lubricating the motor and paper drive mechanism. Not all motors will need to be lubricated.

Verify proper time and date. Correct if necessary: Verify that the time and date displayed on the monitor is correct. If the time and date is not displayed on the monitor, print a strip from the recorder. The time and date should appear on the printed strip. Correct the time and date as necessary.

Replace battery: The battery should be replaced every 24 months. Replace if necessary.

Testing a NIBP monitor with the BP Pump 2.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Verify unit operates on battery: Check that the ac power indicator is lit when the power cord is plugged into an outlet. Unplug the ac power cord and perform the remainder of the functional test on battery power. The ac power indicator should go out when the power cord is unplugged and the battery indicator should light. Be sure to plug the power cord in at the conclusion of the test.

Leak test: Connect a hose and cuff to the NIBP monitor. Place the cuff around a piece of PVC pipe or other sturdy cylindrical object to simulate placement on a limb. Connect a piece of tubing to the pressure port on the BP Pump 2. Connect a tee to this tubing and attach tubing and connectors. Connect the two legs of the tee between the hose and the cuff of the NIBP monitor.

Place the NIBP monitor in service mode to perform the leak test. Select 'LEAK TEST' on the BP Pump 2. Press 'SETUP' to change the test pressure set point. Use the number keys to enter a test pressure of 250 mmHg and then press 'ENT'. Press the soft key labeled 'START' on the analyzer to start the test. Allow the test to run for at least 30 seconds and then press the soft key labeled 'STOP' to end the test. The leak rate should be less than 15 mmHg/min.

Static pressure accuracy: With the NIBP monitor in service mode, select 'Static Pressure' on the BP Pump 2. Press the soft key labeled 'SOURCE'. Set the test pressure on the analyzer to 200 mmHg. Start the test by pressing the soft key labeled 'START'. Compare the pressure displayed on the NIBP monitor with the measured pressure displayed on the analyzer. The measured pressure should be within 3 mmHg of the displayed pressure. For displayed pressure of 200 mmHg, the measured pressure should be between 197 mmHg and 203 mmHg.

Pressure relief test: Place the NIBP monitor into service mode. Select 'PRESSURE RELIEF' on the BP Pump 2 and set the test pressure to 380 mmHg. Press the soft key labeled 'START' to start the test. Once the high-pressure relief valve is triggered on the NIBP monitor, the monitor will vent the pressure from the cuff. Note the pressure at which the relief valve is triggered. The over pressure limit should be less than 330 mmHg. Check the service manual for the exact value.

Dynamic pressure accuracy: Place the NIBP monitor into the normal operating mode. Select 'STANDARD BP' on the BP Pump 2. Press the soft key labeled 'OPTIONS' on the BP Pump 2 to cycle through the available preset blood pressure simulations. Select a blood pressure of 120/80 on the analyzer.

Initiate a blood pressure measurement on the NIBP monitor. The displayed pressure should be within 10 mmHg of the set pressure. For a set blood pressure of 120/80, the systolic pressure should be between 110 mmHg and 130 mmHg and the diastolic pressure should be between 70 mmHg and 90 mmHg. Repeat the measurements for a blood pressure of 200/150 and a blood pressure of 80/50.

Heart rate accuracy: With the NIBP monitor in normal operating mode, select 'STANDARD BP' on the BP Pump 2. Set the simulated blood pressure to 120/80. The simulated heart rate will be 80 bpm. Initiate a blood pressure measurement on the NIBP monitor. The displayed heart rate should be within 5 % of the set heart rate. For a simulated heart rate of 80 bpm, the displayed heart rate should be between 76 bpm and 84 bpm.

Auto interval time: Select a standard blood pressure on the BP Pump 2 of 120/80. Put the NIBP into automatic mode with an interval of 5 minutes. Use a stopwatch or a watch with a second hand to measure the length of time between BP measurements. The measured time should be within 10 % of the set interval. For a set interval of 5 minutes, the measured interval should be between 4 minutes 30 seconds and 5 minutes 30 seconds.

Stop/Cancel/Deflate: Initiate a blood pressure measurement on the NIBP monitor. Allow the cuff to inflate. Stop the measurement on the monitor. The cuff should deflate in less than 10 seconds.

Recorder operation: After taking some blood pressure measurements, print the results with the recorder. Ensure the recorder prints clearly and legibly. If the date and time is present on the recorded strip, Ensure the date and time is accurate.

Alarm function: Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

Select 'STANDARD BP' on the BP Pump 2. Press the soft key labeled 'OPTIONS' on the BP Pump 2 and set the simulated blood pressure to 200/155 mmHg. Set the high alarm limits on the NIBP monitor lower than the simulated pressures. Set the high systolic alarm to 195 mmHg, the high diastolic alarm to 150 mmHg, the high mean pressure alarm to 160 mmHg, and the high heart rate alarm to 75 bpm. Initiate a blood pressure measurement on the NIBP monitor. The high alarms should activate.

If the high heart rate alarm was unable to be set at a low enough value, set the alarm for its lowest value. Select 'PATIENT CONDITIONS' on the BP Pump 2. Use the 'OPTIONS' soft key to cycle through the available simulations until the heart rate is high enough. The 'MILD EXERCISE' simulation has a heart rate of 120 bpm.

Clear the alarms on the NIBP monitor and return the alarm limits to their original settings.

Select 'STANDARD BP' on the BP Pump 2 and set the simulated blood pressure to 60/30. Set the low alarm limits on the NIBP monitor higher than the simulated pressures. Set the low systolic alarm to 65 mmHg, the low diastolic alarm to 35 mmHg, the low mean pressure alarm to 45 mmHg, and the low heart rate alarm to 85 bpm. Initiate a blood pressure measurement on the NIBP monitor. The high alarms should activate.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any settings that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions. Plug in the power cord to ensure the battery remains charged.

Patient monitor

Patient monitors measure and display physiologic parameters reflecting a patient's clinical condition. These monitors may sometimes be referred to as vital signs monitors. Patient monitors contain circuitry to acquire and process information from physiological sensors, such as electrodes, catheters, and transducers. The monitors are usually customizable as to what parameters are able to be measured, and a single model may have several possible configurations. Most commonly these monitors display at least ECG waveforms, SpO_2, and blood pressure. Each component of the monitor should be tested to Ensure the device is accurate.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	3
Device is used to deliver direct treatment to the patient	4	
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	3
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	1
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		10
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

Patient monitor procedure

Estimated time: 50 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
MPS450 Multiparameter Simulator (or equivalent)
BP Pump 2 NIBP Analyzer (or equivalent)
Index 2 SpO_2 Analyzer (or equivalent)
Stopwatch or watch with a second hand
Cables to connect to MPS450
Tubing and connectors to connect to BP Pump 2
PVC pipe to attach BP cuff to
Gas with a known quantity of CO_2

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ

continued on page 105

 ©University of Vermont, Rev. 2 – Confidential

Patient monitor procedure

Estimated time: 50 minutes

continued from page 104

Test Result				
Pass	Fail	N/A		
Preventive maintenance				
			Check condition of tubing, cuffs, and hoses	
			Clean recorder paper compartment, rollers and paper guides	
			Lubricate motor and paper drive mechanism	
			Verify proper time and date, correct if necessary	
			Replace battery every 24 months	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify unit operates on battery	
			Heart rate accuracy	± 5 %
			Amplitude accuracy	± 5 %
			Recorder speed	± 4 %
			Respiration rate accuracy	± 5 %
			Leak test	≤ 15 mmHg/min
			Static pressure accuracy	± 3 mmHg
			Pressure relief test	≤ 330 mmHg
			Dynamic pressure accuracy	± 10 mmHg
			Auto interval time	± 10 %
			Stop/Cancel/Deflate	≤ 10 sec
			SpO2 accuracy	± 3 %
			Invasive pressure accuracy	± 5 %
			Temperature accuracy	± 0.3 C
			Carbon dioxide concentration accuracy	± 0.4 vol %
			Alarm function	
			Complete model-specific performance testing	

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage.

Preventive maintenance

Check condition of tubing, cuffs, and hoses: Inspect hoses and cuffs for signs of wear. Look for holes, cracks, and dry rot. Ensure that all connections are secure.

Clean recorder paper compartment, rollers, and paper guides: Inspect the rollers and paper guides and remove any debris. Check for bits of torn paper caught in the rollers.

Lubricate motor and paper drive mechanism: Follow the manufacturer's instructions in the service manual for lubricating the motor and paper drive mechanism. Not all motors will need to be lubricated.

Verify proper time and date. Correct if necessary: Verify that the time and date displayed on the monitor is correct. If the time and date is not displayed on the monitor, print a strip from the recorder. The time and date should appear on the printed strip. Correct the time and date as necessary.

Replace battery: The battery should be replaced every 24 months. Replace if necessary.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Verify unit operates on battery: Check that the ac power indicator is lit when the power cord is plugged into an outlet. Unplug the ac power cord and perform the remainder of the functional test on battery power. The ac power indicator should go out when the power cord is unplugged and the battery indicator should light. Be sure to plug the power cord in at the conclusion of the test.

Heart rate accuracy: Connect the patient leads to the lead connectors on the MPS450. Set the heart rate on the MPS450 to 60 bpm. Press '1' ('NSR'), and then use the soft keys marked 'UP' and 'DOWN' to change the heart rate to 60 bpm.

The heart rate should be within 5 % of the set rate. For a simulated heart rate of 60 bpm, the displayed rate should be between 57 bpm and 63 bpm. Set the heart rate on the MPS450 to 120 bpm. The displayed heart rate should be between 114 bpm and 126 bpm.

Amplitude accuracy: With the patient leads connected to the MPS450, input a normal sinus rhythm by pressing '1' ('NSR'). Press the soft key marked 'SEL' to select AMPL. Use the soft keys marked up and down to change the amplitude to 1.0 mV. Set the sensitivity on the electrocardiograph to 20 mm/mV. Record a strip on the electrocardiograph.

Measure the height of the QRS peak. The measured amplitude should be within 5 % of the set amplitude. For an amplitude setting of 1 mV and a sensitivity of 20 mm/mV, the peak should be between 19 mm and 21 mm.

Heart rate alarms: Set the high heart rate alarm on the monitor to 120 bpm. Set the low heart rate alarm on the monitor to 40 bpm. Adjust the heart rate on the MPS450 to 140 bpm. The high rate alarm should activate. Return the heart rate on the MPS450 to 60 bpm and clear the alarm. Adjust the heart rate on the MPS450 to 30 bpm. The low rate alarm should activate. Return the heart rate on the MPS450 to 60 bpm and clear the alarm. Return the alarm limits on the monitor to their original settings.

Recorder speed: Set the heart rate on the MPS450 to 60 bpm. Record a strip on the electrocardiograph. Measure the distance between the peaks of the QRS complex. With a recorder speed of 25 mm/sec, the QRS peaks should be between 24 mm and 26 mm apart.

Respiration rate accuracy: Set the respiration rate on the MPS450 to 20 breaths/min. Press '2' ('RESP') and then use the soft keys to change the respiration rate. The respiration rate should be within 5 % of the set rate. For a simulated respiration rate of 20 breaths/min, the displayed rate should be between 19 breaths/min and 21 breaths/min.

Respiration alarms: Set the high respiration rate alarm on the monitor to 60 breaths/min. Set the low respiration rate alarm on the monitor to 20 bpm. Adjust the respiration rate on the MPS450 to 80 breaths/min. The high rate alarm should activate. Bring down the respiration rate on the MPS450 to 30 breaths/min and clear the alarm. Adjust the respiration rate on the MPS450 to 15 bpm. The low rate alarm should activate. Bring down the respiration rate on the MPS450 to 20 breaths/min and clear the alarm. Return the alarm limits on the monitor to their original settings.

To simulate an apnea condition, press the soft key button 'APNE'. Use the soft keys marked 'PREV' and 'NEXT' to cycle through the apnea durations and select 'CONTINUOS'. Press the soft key labeled 'RUN' to start the apnea condition. To stop the apnea condition and return to normal respiration, press the soft key labeled 'STOP'. The alarm should sound for an apnea condition. Most monitors will alarm within 30 seconds.

Leak test: Connect a hose and cuff to the NIBP monitor. Place the cuff around a piece of PVC pipe or other sturdy cylindrical object to simulate placement on a limb. Connect a piece of tubing to the pressure port on the BP Pump 2. Connect a tee to this tubing and attach tubing and connectors. Connect the two legs of the tee between the hose and the cuff of the NIBP monitor.

Place the NIBP monitor in service mode to perform the leak test. Select 'LEAK TEST' on the BP Pump 2. Press 'SETUP' to change the test pressure set point. Use the number keys to enter a test pressure of 250 mmHg and then press 'ENT'. Press the soft key labeled 'START' on the analyzer to start the test. Allow the test to run for at least 30 seconds and then press the soft key labeled 'STOP' to end the test. The leak rate should be less than 15 mmHg/min.

Static pressure accuracy: With the NIBP monitor in service mode, select 'STATICPressure' on the BP Pump2. Press the soft key labeled 'SOURCE'. Set the test pressure on the analyzer to 200 mmHg. Start the test by pressing the soft key labeled 'START'. Compare the pressure displayed on the NIBP monitor with the measured pressure displayed on the analyzer. The measured pressure should be within 3 mmHg of the displayed pressure. For displayed pressure of 200 mmHg, the measured pressure should be between 197 mmHg and 203 mmHg.

Pressure relief test: Put the NIBP monitor into service mode. Select 'PRESSURE RELIEF' on the BP Pump 2 and set the test pressure to 380 mmHg. Press the soft key labeled 'START' to start the test. The test will end when the high-pressure relief valve is triggered on the NIBP monitor and the monitor vents the pressure from the cuff. Note the pressure at which the relief valve is triggered. The over pressure limit should be less than 330 mmHg. Check the manufacturer's service manual for the exact value.

Dynamic pressure accuracy: Place the NIBP monitor into the normal operating mode. Select 'STANDARD BP' on the BP Pump 2. Press the soft key labeled 'OPTIONS' on the BP Pump 2 to cycle through the available preset blood pressure simulations. Select a blood pressure of 120/80 on the analyzer.

Initiate a blood pressure measurement on the NIBP monitor. The displayed pressure should be within 10 mmHg of the set pressure. For a set blood pressure of 120/80, the systolic pressure should be between 110 mmHg and 130 mmHg and the diastolic pressure should be between 70 mmHg and 90 mmHg. Repeat the measurements for a blood pressure of 200/150 and a blood pressure of 80/50.

Auto interval time: Select a standard blood pressure on the BP Pump 2 of 120/80. Put the NIBP into automatic mode with an interval of 5 minutes. Use a stopwatch or a watch with a second hand to measure the length of time between BP measurements. The measured time should be within 10 % of the set interval. For a set interval of 5 minutes, the measured interval should be between 4 minutes 30 seconds and 5 minutes 30 seconds.

Stop/Cancel/Deflate: Initiate a blood pressure measurement on the NIBP monitor. Allow the cuff to inflate. Stop the measurement on the monitor. The cuff should deflate in less than 10 seconds.

NIBP alarms: Select 'STANDARD BP' on the BP Pump 2. Press the soft key labeled 'OPTIONS' on the BP Pump 2 and set the simulated blood pressure to 200/155. Set the high alarm limits on the NIBP monitor lower than the simulated pressures. Set the high systolic alarm to 195 mmHg, the high diastolic alarm to 150 mmHg, and the high mean pressure alarm to 160 mmHg. Initiate a blood pressure measurement on the NIBP monitor. The high alarms should activate. Clear the alarms on the monitor and return the alarm limits to their original settings.

Select 'STANDARD BP' on the BP Pump 2 and set the simulated blood pressure to 60/30. Set the low alarm limits on the NIBP monitor higher than the simulated pressures. Set the low systolic alarm to 65 mmHg, the low diastolic alarm to 35 mmHg, and the low mean pressure alarm to 45 mmHg. Initiate a blood pressure measurement on the NIBP monitor. The low alarms should activate.

O_2 accuracy: Attach a finger probe to the pulse oximeter. Place the finger sensor on the finger simulator of the Index 2 simulator. From the main menu of the Index 2, press the soft key labeled 'MORE' for the second menu and then press the soft key labeled 'MAKE'. Use the plus and minus keys to scroll through the available makes. Select the make of the pulse oximeter to be tested. When the correct make appears on the screen, press the 'ESC' key to return to the main menu.

From the main menu, press the soft key labeled 'SIM' to enter the simulation mode. Begin a manual simulation by pressing the soft key labeled 'MAN'. Use the plus and minus keys to adjust the O_2 level and heart rate. Set the heart rate to 60 bpm to match the heart rate from the MPS450. Adjust the O_2 level on the Index 2 to 96 %. Initiate a measurement on the pulse oximeter. The displayed SpO_2 value should be within 3 digits of the set value. For a simulated SpO_2 of 96 %, the displayed value should be between 93 % and 99 %.

SpO_2 alarms: Set the high O_2 alarm on the pulse oximeter to 98 %. Set the low O_2 alarm to 90 %. Set the Index 2 for a manual simulation with the SpO_2 at 96 % and the heart rate 80 bpm. Initiate a measurement on the pulse oximeter. Adjust the SpO_2 on the Index 2 to 100 %. The high 02 alarm on the pulse oximeter should activate. Bring the SpO_2 back down to 96 % and clear the alarm. Adjust the SpO_2 on the Index 2 to 88 %. The low 02 alarm on the pulse oximeter should activate. Bring the SpO_2 back to 96 % and clear the alarm.

Set the high heart rate alarm on the pulse oximeter to 120 bpm and set the low heart rate alarm to 60 bpm. Adjust the heart rate on the Index 2 to 125 bpm. The high heart rate alarm should activate. Return the heart rate to 80 bpm and clear the alarm. Adjust the heart rate on the Index 2 to 55 bpm. The low heart rate alarm should activate. Return the heart rate to 80 bpm and clear the alarm. Return all alarm limits to their original settings.

Invasive pressure accuracy: Set the blood pressure transducer sensitivity on the MPS450 according to manufacturer requirements. Press the button labeled '0' ('SETUP') to access the set up menu. Press the soft key labeled 'BP SENSE' and then use the soft keys to toggle the sensitivity between 5 µV/V/mmHg and 40 µV/V/mmHg.

Press the key labeled '3' ('BP') to enter the blood pressure menu on the MPS450. Press the 'BP1' soft key and then press 'ZERO' to zero the channel if necessary. Connect the invasive blood pressure cable to the BP1 port on the side of the MPS450.

Press the 'DYNA' soft key to start a dynamic pressure simulation. Select an arterial pressure of 120/80. Press 'RUN' to begin the simulation. The pressure displayed on the monitor should be within 5 % of the set pressure. For a simulated pressure of 120/80, the displayed systolic pressure should be between 114 mmHg and 126 mmHg and the diastolic pressure should be between 76 mmHg and 84 mmHg.

Invasive pressure alarms: Set the high-pressure alarm limits on the monitor lower than 120/80. Set the high systolic alarm limit to 115 mmHg and the high diastolic alarm limit to 75 mmHg. The high alarms should activate. Clear the alarms on the monitor and return the alarm limits to their original settings.

Set the low-pressure alarm limits on the monitor higher than 120/80. Set the low systolic alarm limit to 125 mmHg and the low diastolic alarm limit to 85 mmHg. The low alarm should activate. Clear the alarms on the monitor and return the alarm limits to their original settings.

Temperature accuracy: Connect the temperature cable to the CO/TEMP port on the side of the MPS450. Press the key labeled '7' ('TEMP') to start the temperature simulation. Use the up and down keys to set the temperature to 37 °C. The temperature displayed on the monitor should be within 0.3 °C of the set temperature. For a simulated temperature of 37 °C, the displayed temperature should be between 36.7 °C and 37.3 °C.

Temperature alarms: Set the high temperature alarm on the monitor to 38 °C and set the low temperature alarm to 34 °C. Adjust the temperature on the MPS450 to 40 °C. The high alarm should activate. Return the temperature on the MPS450 to 37 °C and clear the alarm. Adjust the temperature on the MPS450 to 24 °C. The low temperature alarm should activate. Return the temperature on the MPS450 to 37 °C and clear the alarm.

Carbon dioxide concentration accuracy: Connect the gas canister to the patient sample line of the monitor. Inject the gas into the sample line. The displayed CO_2 concentration should be within 0.4 vol% of the gas sample. For a gas sample with 5.0 % CO_2, the monitor should display a CO_2 concentration between 4.6 % and 5.4 %.

Carbon dioxide alarm: Set the high carbon dioxide alarm limit on the monitor to below the CO_2 concentration of the test gas. Inject the gas into the patient sample tubing. The high CO_2 concentration alarm should activate. Return the alarm limit to its original setting and clear the alarm.

Alarm function: Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any settings that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions. Plug in the power cord to ensure the battery remains charged.

PCA pump

PCA, patient controlled analgesic, pumps are infusion pumps that deliver an analgesic drug on when requested by the patient. These pumps typically utilize tubing designed specifically for use with PCA infusion pumps, which is then connected to an infusion catheter or other infusion device such as an implanted infusion port. PCA pumps can typically be programmed to deliver in one of three ways, as a continuous infusion, as a demand dose only, or as a continuous infusion with a demand dose. A demand dose is initiated by the patient pressing a button. A predetermined amount of the drug is delivered rapidly as a bolus. PCA pumps have a timing function that allows a 'lockout interval', to prevent an overdose of the analgesic.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	4
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	3
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	
A significant history of incidents exists	2	2
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		12
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

 ©University of Vermont, Rev. 2 – Confidential

FLUKE®
Biomedical

PCA pump procedure
Estimated time: 45 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date:_____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
IDA 4 Plus Infusion Device Analyzer (or equivalent)
PCA trigger interface
Tubing set for PCA pump
Reservoir to connect to tubing set (bag, bottle, or syringe)
20 cc or larger syringe
3 way stopcock
Cable to connect PCA trigger interface to PCA pump
Tubing and connectors to connect infusion set to IDA4 Plus
Tubing and connectors to connect to IDA 4 Plus

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ

continued on page 112

PCA pump procedure

Estimated time: 45 minutes

continued from page 111

Test Result				
Pass	Fail	N/A		
Preventive maintenance				
			Clean flow detector	
			Replace battery every 24 months	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify unit operates on battery	
			Door lock	
			Pole clamp function	
			Load dose	± 10 %
			Flow rate accuracy	± 10 %
			Volume accuracy	± 10 %
			PCA dose	± 10 %
			Lock out interval	± 5 %
			Dose limit	
			KVO rate	± 10 %
			Occlusion detection pressure	± 1 psi
			Alarm function	
			Complete model-specific performance testing	

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage.

Preventive maintenance

Clean flow detector: Inspect the flow detector on the PCA pump. Clean any debris from the flow sensor.

Replace battery: The battery should be replaced every 24 months. Replace if necessary.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Verify unit operates on battery: Check the ac power indicator is lit when the power cord is plugged into an outlet. Unplug the ac power cord and perform the remainder of the functional test on battery power. The ac power indicator should go out when the power cord is unplugged and the battery indicator should light. Be sure to plug the power cord in at the conclusion of the test.

Door lock: Inspect the door assembly. Ensure the door swings smoothly and locks with the key.

Pole clamp function: Check the physical condition of the pole clamp. The pole clamp should be securely fastened to the pump. The clamp mechanism should move freely. The pole clamp should secure the pump to the IV pole. Ensure the pole clamp cannot be released when the pump is locked.

Load dose: Fill the reservoir with a 1 % detergent solution in de-ionized water. Prepare a 1 % stock solution of detergent such as Cole-Parmer Micro-90 in volume using de-ionized water; this may be stored in a closed vessel for up to 6 months. This solution should then be diluted 10:1 with de-ionized water for daily use. If the water used causes too much foaming, a 20:1 dilution is recommended. Do not use tap water or solutions intended for patient use, as these may harm the transducers in the IDA 4 Plus.

Connect the infusion tubing to the reservoir. Prime the set so that there is no air in the tubing. With the tubing draining into a container or sink, open the flow control mechanism on the tubing set. Hold the reservoir high enough above the tubing so that fluid flows through the tubing under the force of gravity. Allow fluid to flow through the tubing until no air bubbles can be seen in the tubing. Insert the set into the pump. Connect the three-way stopcock to the channel 1 port on the IDA 4 Plus. Connect the patient infusion tubing to one port of the stopcock. Fill the syringe with the detergent solution and connect the syringe to the other port of the stopcock. Connect a piece of tubing to the drain port of channel 1 and run the tubing into a container to catch the used solution.

Connect the PCA trigger interface box to the connector on the back of the IDA 4 Plus. Attach a cable from channel 1 of the trigger output to the patient dose cable port on the PCA pump. If multiple PCA pumps are to be tested simultaneously, additional pumps can be connected to the other channels on the interface box.

From the status screen on the IDA 4 Plus, select 'UTIL' to enter the utilities menu and then select 'TEST PARAMATERS' from the utilities menu. Use the arrow keys to adjust the PCA Pre Trig Time to 60 seconds. This is the time prior to the expiry of the lock out interval that the IDA 4 Plus will begin attempting to trigger the PCA dose.

Return to the main set-up screen and use the arrow keys to select 'SETUP' under channel 1. Use the arrow keys on the set-up menu to select 'PCA'. Use the arrow keys to enter the basal flow rate, total volume, bolus volume, lockout time, and loading dose to be tested. Enter a basal flow rate of 15 mL/hr. Enter a total volume of 20 mL. Enter a bolus volume of 1 mL. Enter a lockout time of 5 minutes 0 seconds. Enter a loading dose of 1 mL. After the test information is entered, the PCA test screen will appear. Use the arrow keys to highlight 'PRIME'. Close the stopcock port connected to the infusion tubing, leaving the ports to the syringe and the IDA 4 Plus open. Inject the solution in the syringe into the IDA 4 Plus until 'START' appears on the screen. Select 'AutoSTART'. The IDA 4 Plus will start the flow test when it detects flow from the pump. Close the port to the syringe, leaving the ports to the tubing and the IDA 4 Plus open.

Set up the PCA pump as entered on the IDA 4 Plus. Set the continuous flow rate to 15 mL/hr, the bolus volume to 1 mL, the lockout time to 5 minutes, and the loading dose to 1 mL. If the PCA pump has a dose limit, set the limit to 2 mL.

Start the pump. The loading dose will appear on the PCA test screen. Verify that the actual bolus volume is within 10 % of the set volume. For a dose of 1 mL, the measure volume should be between 0.9 mL and 1.1 mL.

The IDA 4 Plus is equipped with four channels to analyze infusion devices. Four pumps can be run simultaneously.

Flow rate accuracy: Continue to run the PCA pump as described above. The IDA 4 Plus will display the basal flow rate. Allow the pump to deliver at least 10 mL and then compare the measured flow rate to the set rate. The measured flow rate should be within 10 % of the set rate. For a flow rate of 15 mL/hr, the measured flow rate should be between 13.5 mL/hr and 16.5 mL/hr.

Volume accuracy: Continue to run the PCA pump as described above. The IDA 4 Plus will display the total volume delivered. Allow the pump to deliver at least 10 mL and then compare the measured volume displayed on the analyzer to the volume displayed on the pump. The measured volume should be within 10 % of the pump volume. For a volume of 10 mL, the measured volume should be between 9 mL and 11 mL.

PCA dose: Continue to run the PCA pump as described above. The IDA 4 Plus will display the delivered bolus volume. Allow the pump to deliver a bolus and then compare the measured volume displayed on the analyzer to the set volume. Verify that the actual bolus volume is within 10 % of the set volume. For a dose of 1 mL, the measure volume should be between 0.9 mL and 1.1 mL.

Lock out interval: Continue to run the PCA pump as described above. The IDA 4 Plus will attempt to trigger a PCA dose 60 seconds before the lock out time expires. Allow the PCA pump to deliver at least 2 doses. The interval time will be displayed on the IDA 4 Plus. The measured interval time should be within 5 % of the set lock out interval. For a lock out interval of 5 minutes, the measured interval time should be between 4 minutes 45 seconds and 5 minutes 15 seconds.

Dose limit: Continue to run the PCA pump as described above and allow it to deliver 20 mL. When the pump reaches the dose limit, the dose limit alarm should activate. The pump should no longer deliver the continuous rate, nor allow any boluses. The pump may continue to deliver a KVO rate.

KVO rate: When the PCA pump reaches its dose limit, it will go into a KVO rate to supply a very low flow rate in order to keep the vein open if another infusion needs to be given. Measure the KVO rate using the 'FLOW' function on the IDA 4 Plus.

Allow the pump to reach its dose limit, but do not stop the pump. Instead, silence the alarm and let the pump run. Enter the 'FLOW' screen on the IDA 4 Plus to measure the KVO rate. It may take several minutes for the analyzer to be able to measure the low rate. The measured rate should be within 10 % of the infusion pump's KVO rate. Check the service manual for the exact rate. For a KVO rate of 1 mL/hr, the measured rate should be between 0.9 mL/hr and 1.1 mL/hr.

Occlusion detection pressure: From the channel set up menu on the IDA 4 Plus, select 'OCCLUSION'. Prime the IDA 4 Plus with the syringe if necessary. Set the flow rate on the PCA pump to 15 mL/hr and start the pump. Select 'START' on the IDA 4 Plus. Select 'END' on the IDA 4 Plus when the pump alarms occlusion. Note the pressure at which the pump alarms. Compare the measured pressure to the occlusion pressure of the pump. The occlusion pressure will be specific to the model. Check the service manual for the specific pressure. The measured occlusion pressure should be within 1 psi of the pump's occlusion pressure. For an occlusion pressure of 20 psi, the measured pressure should be between 19 psi and 21 psi.

Alarm function: Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

Set the continuous rate on the pump to 15 mL/hr. and start the pump. Occlude the tubing between the reservoir and the pump. The tubing can be occluded either by closing a clamp attached to the tubing or by pinching the tubing with a set of hemostats or pliers. The pump should alarm upstream occlusion.

Clear the alarm and restart the pump. Occlude the tubing after the pump. The pump should alarm downstream occlusion. Clear the alarm.

If the pump is equipped with an air detector, introduce air into the tubing. This can be done by turning the reservoir upside down until a bubble of air is pulled through the tubing. Turn the reservoir right side up. When the air bubble gets to the pump, the pump should alarm air in line. Clear the alarm. Remove the tubing from the pump and prime the set so that there is no air in the tubing. Reinsert the tubing set into the pump and restart the pump.

Simulate an empty container situation either by turning the reservoir upside down so that no fluid can get to the tubing, or by removing the tubing from the reservoir. The pump should alarm when no fluid flow is detected.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any settings that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions. Plug in the power cord to ensure the battery remains charged.

Phototherapy unit

Phototherapy units irradiate patients with light to produce beneficial bioeffects. Most commonly, these devices are used to treat hyperbilirubinemia, jaundice, in newborns. Phototherapy units for this purpose are sometimes referred to as bili lights. Blue light, typically with a wavelength between 420 nm and 480 nm, is used to break down the bilirubin. A photo oxidation process causes the converts water-insoluble bilirubin to water-soluble compounds that can be excreted. Most commonly, phototherapy units are seen as overhead units that apply the light radiation from a lamp. Phototherapy units are also available as pad or blanket with a separate light source connected by a fiberoptic cable.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	4
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	3
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	3
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	1
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		12
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

 ©University of Vermont, Rev. 2 – Confidential

FLUKE®
Biomedical

Phototherapy unit procedure

Estimated time: 20 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
DALE40 Phototherapy Radiometer (or equivalent)
Stopwatch or watch with a second hand

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Inspect bulbs	
			Complete model-specific preventive maintenance	
Performance testing				
			Timer accuracy	± 0.5 %
			Output accuracy	≥ 4.5 µW/cm2/nm (≥ 198 µW/cm2 @ 44 nm bandwidth) ≤ 40 µW/cm2/nm (≤ 1760 µW/cm2 @ 44 nm bandwidth)
			Alarm function	
			Complete model-specific performance testing	

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage.

Preventive maintenance

Inspect bulbs: Inspect the phototherapy unit for broken or burned out bulbs. Replace as necessary.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Timer accuracy: Set the timer for 2 minutes. Initiate treatment and begin timing with the stopwatch. Initiate phototherapy treatment and begin timing with a stopwatch or a watch with a second hand. The treatment timer should sound within 5 % of the measured time. For a set time of 120 seconds, the actual measured time should be between 114 seconds and 126 seconds. Verify that treatment stops when the timer stops.

Output accuracy: Initiate a phototherapy treatment. Place the photodetector probe facing the light about 18 inches (45.7cm) from the light source. The irradiance will be displayed on the Dale40. The measured irradiance should be between 198 µW/cm2 and 1760 µW/cm2. Refer to the phototherapy unit's service manual for the unit's output range.

Alarm function: Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any settings that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions.

Pneumatic tourniquet

Tourniquets are used to prevent blow flow to a limb during surgery. A pneumatic tourniquet consists of an inflatable cuff, an air pump, pressure sensors, and a processor to control cuff pressure. The cuff is placed on the limb proximal to the operative site. The cuff is then inflated to a preset pressure, occluding vessels and arteries and preventing blow flow past the cuff. The pneumatic tourniquet measures and displays the cuff pressure and inflation time. The cuff itself is typically dual chambered, allowing for alternation of the pressure site.

Recommended functional test frequency: semiannual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	4
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	
Device failure could result in severe injury to, or death of, patient or user	4	4
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	3
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	
A significant history of incidents exists	2	2
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		14
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		2

Pneumatic tourniquet procedure

Estimated time: 35 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
DPM 4 Pressure Meter (or equivalent)
Stopwatch or watch with a second hand
Squeeze bulb with bleed valve
Tubing and connectors to connect to DPM 4
PVC pipe to attach tourniquet cuff to

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Check condition of tubing, cuffs, and hoses	
			Replace battery every 24 months	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify unit operates on battery	
			Verify function of control valve	
			Controller stability	± 10 mmHg after 15 min
			Cuff pressure accuracy	± 5 %
			Timer accuracy	± 2 min after 15 min
			Maximum cuff pressure	≤ 550 mmHg or manufacturer's specification
			Complete model-specific performance testing	

 ©University of Vermont, Rev. 2 – Confidential

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage.

Preventive maintenance

Check condition of tubing, cuffs, and hoses: Inspect hoses and cuffs for signs of wear. Look for holes, cracks, and dry rot. Ensure that all connections are secure.

Replace battery: The battery should be replaced every 24 months. Replace if necessary.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Verify unit operates on battery: Check that the ac power indicator is lit when the power cord is plugged into an outlet. Unplug the ac power cord and perform the remainder of the functional test on battery power. The ac power indicator should go out when the power cord is unplugged and the battery indicator should light. Be sure to plug the power cord in at the conclusion of the test.

Verify function of control valve: Connect hoses and cuffs to the pneumatic tourniquet. Place the cuffs around a piece of PVC pipe or other sturdy cylindrical object to simulate placement on a limb. Inflate the proximal cuff. Ensure the tourniquet is able to hold pressure. Inflate the distal cuff. Again, Ensure the tourniquet is able to hold pressure and then deflate the cuff. Inflate both cuffs together. Hold the pressure for a short time and then deflate. If the tourniquet has multiple channels, repeat the test for each channel.

Controller stability: Attach a 3-way connector to the pressure port on the DPM 4. Attach a squeeze ball to one leg of the connector. Ensure the bleed valve on the squeeze ball is closed. Attach another 3-way connector to the other leg. Connect the remaining two legs between the hose and the cuff of the tourniquet.

Set the pressure on the pneumatic tourniquet to 400mmHg and inflate the cuff. Allow the pressure to stabilize for 15 minutes. After 15 minutes, the pressure should be between 390 mmHg and 410 mmHg.

Cuff pressure accuracy: Set the pressure on the pneumatic tourniquet to 200 mmHg and inflate the cuff. Observe the pressure for at least two minutes to Ensure the pressure remains stable. The displayed pressure should be within 5 % of the measured pressure. For a displayed pressure of 200 mmHg, the measured pressure should be between 190 mmHg and 210 mmHg. Set the cuff pressure to 450 mmHg and repeat the measurement. At this setting, the measured pressure should be between 427.5 mmHg and 472.5 mmHg.

Timer accuracy: Inflate the cuff on the pneumatic tourniquet. Use a stopwatch or a watch with a second hand to measure the elapsed time. Allow the cuff to remain inflated for 15 minutes. The elapsed time displayed on the tourniquet should be between 13 and 17 minutes.

Maximum cuff pressure: Set the pressure on the pneumatic tourniquet to its maximum setting. Inflate the cuff and allow the pressure to stabilize. Use the squeeze ball to slowly increase the pressure in the cuff until the pressure relief valve vents the pressure in the cuff. Note the pressure at which the relief valve is triggered. The over pressure limit should be less than 550 mmHg. Check the manufacturer's service manual for the exact value.

Alarm function: Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

Inflate the tourniquet cuff. Slowly open the bleed valve on the squeeze ball to simulate a leak. The tourniquet leak alarm should activate.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any settings that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions. Plug in the power cord to ensure the battery remains charged.

Pulse oximeter

A pulse oximeter non-invasively measures the oxygen saturation of a patient's blood. A pulse oximeter consists of a red and an infrared light source, photo detectors, and probe to transmit light through a translucent, pulsating arterial bed, typically a fingertip or earlobe. Oxygenated hemoglobin (O2Hb) and deoxygenated hemoglobin (HHb) absorb red and infrared light differently. The percent saturation of hemoglobin in arterial blood can be calculated by measuring light absorption changes caused by arterial blood flow pulsations.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	3
Device is used to deliver direct treatment to the patient	4	
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	3
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	1
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		10
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

Pulse oximeter procedure

Estimated time: 20 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
Index 2 SpO_2 Analyzer (or equivalent)

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Clean recorder paper compartment, rollers and paper guides	
			Lubricate motor and paper drive mechanism	
			Verify proper time and date, correct if necessary	
			Replace battery every 24 months	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify unit operates on battery	
			Heart rate accuracy	± 5 %
			SpO_2 accuracy	± 3 %
			Recorder operation	
			Alarm function	
			Complete model-specific performance testing	

 ©University of Vermont, Rev. 2 – Confidential

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage.

Preventive maintenance

Clean recorder paper compartment, rollers, and paper guides: Inspect the rollers and paper guides and remove any debris. Check for bits of torn paper caught in the rollers.

Lubricate motor and paper drive mechanism: Follow the manufacturer's instructions in the service manual for lubricating the motor and paper drive mechanism. Not all motors will need to be lubricated.

Pulse oximeter connected to Index 2 SpO_2 simulator.

Verify proper time and date. Correct if necessary: Verify that the time and date displayed on the monitor is correct. If the time and date is not displayed on the monitor, print a strip from the recorder. The time and date should appear on the printed strip. Correct the time and date as necessary.

Replace battery: The battery should be replaced every 24 months. Replace if necessary.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Verify unit operates on battery: Check that the ac power indicator is lit when the power cord is plugged into an outlet. Unplug the ac power cord and perform the remainder of the functional test on battery power. The ac power indicator should go out when the power cord is unplugged and the battery indicator should light. Be sure to plug the power cord in at the conclusion of the test.

Heart rate accuracy: Attach a finger probe to the pulse oximeter. Place the finger sensor on the finger simulator of the Index 2 simulator. From the main menu of the Index 2, press the soft key labeled 'MORE' for the second menu and then press the soft key labeled 'MAKE'. Use the plus and minus keys to scroll through the available makes. Select the make of the pulse oximeter to be tested. When the correct make appears on the screen, press the 'ESC' key to return to the main menu.

From the main menu, press the soft key labeled 'SIM' to enter the simulation mode. Begin a manual simulation by pressing the soft key labeled 'MAN'. Use the plus and minus keys to adjust the O_2 level and heart rate. Set the heart rate to 80 bpm. Turn on the pulse oximeter and initiate a measurement. The displayed heart rate should be within 5 % of the set heart rate. For a simulated heart rate of 80 bpm, the displayed heart rate should be between 76 bpm and 84 bpm.

O_2 accuracy: Adjust the O_2 level on the Index 2 to 96 %. Initiate a measurement on the pulse oximeter. The displayed SpO_2 value should be within 3 % of the set value. For a simulated SpO_2 of 96 %, the displayed value should be between 93 % and 99 %.

Recorder operation: After taking some O_2 measurements, print the results with the recorder. Ensure the recorder prints clearly and legibly. If the date and time is present on the recorded strip, Ensure the date and time is accurate.

Alarm function: Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

Set the high O_2 alarm on the pulse oximeter to 98 %. Set the low O_2 alarm to 90 %. Set the Index 2 for a manual simulation with the SpO_2 at 96 % and the heart rate 80 bpm. Initiate a measurement on the pulse oximeter. Adjust the SpO_2 on the Index 2 to 100 %. The high O_2 alarm on the pulse oximeter should activate. Bring the SpO_2 back down to 96 % and clear the alarm. Adjust the SpO_2 on the Index 2 to 88 %. The low O_2 alarm on the pulse oximeter should activate. Bring the SpO_2 back to 96 % and clear the alarm.

Set the high heart rate alarm on the pulse oximeter to 120 bpm and set the low heart rate alarm to 60 bpm. Adjust the heart rate on the Index 2 to 125 bpm. The high heart rate alarm should activate. Return the heart rate to 80 bpm and clear the alarm. Adjust the heart rate on the Index 2 to 55 bpm. The low heart rate alarm should activate. Return the heart rate to 80 bpm and clear the alarm. Return all alarm limits to their original settings.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any settings that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions. Plug in the power cord to ensure the battery remains charged.

Radiant warmer

Radiant warmers provide thermal stability to infants. They are used to provide thermal support to newborns and critically ill infants and also for infants undergoing long procedures in a cool environment. Unlike incubators, radiant warmers are not enclosed, allowing direct access to the infant. These devices typically consist of an overhead heater and a temperature probe. Typically, the radiant warmer is set to a temperature and a temperature probe is attached to the infant's skin. The heater will turn on while the infant's skin temperature is below the set temperature. When the skin temperature reaches the set temperature, the heater turns off.

Recommended functional test frequency: semiannual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	4
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	
Device failure could result in severe injury to, or death of, patient or user	4	4
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	3
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	
A significant history of incidents exists	2	2
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		14
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		2

Radiant warmer procedure

Estimated time: 35 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
INCU incubator analyzer (or equivalent)

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Clean vents and filters	
			Replace battery every 24 months	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify unit operates on battery	
			Fan operation	
			Temperature accuracy	± 0.3 °C
			Temperature alarms	
			Alarm function	
			Complete model-specific performance testing	

 ©University of Vermont, Rev. 2 – Confidential

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage.

Preventive maintenance

Clean vents and filters: Inspect vents and air filters. Clean or replace filters as necessary. Ensure that filters are installed properly.

Replace battery: The battery should be replaced every 24 months. Replace if necessary.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Verify unit operates on battery: Check that the ac power indicator is lit when the power cord is plugged into an outlet. Unplug the ac power cord and perform the remainder of the functional test on battery power. The ac power indicator should go out when the power cord is unplugged and the battery indicator should light. Be sure to plug the power cord in at the conclusion of the test.

Fan operation: Inspect the fan blades for damage. Look for chips, warping, melting, and missing blades. Ensure there is adequate clearance around the fan assembly. Look for signs of rubbing around the fan housing. Lubricate the fan motor per the manufacturer's specification. Follow the manufacturer's instructions in the service manual for lubricating the pump motor. Not all motors will need to be lubricated.

INCU placed in radiant warmer.

INCU with radiant warmer adapter.

Temperature accuracy: Set the warmer temperature to 34 °C. Place the INCU in the center of the incubator. Place the T1 and T3 temperature probes so that they are placed vertically in opposite corners. Clip the T2 probe to the underside of the radiant baby adapter. Place the radiant baby adapter on top of the INCU and align it with the heater in the warmer.

Place the skin temperature probe from the warmer in close proximity to the T2 sensor. Allow the temperature to stabilize. Press the 'SELECT' button on the INCU to cycle through the readings. Place the skin temperature probe in close proximity to the T2 sensor on the INCU. Allow the incubator temperature to stabilize. The measured temperature on the T2 sensor should be within 0.3 °C of the displayed skin temperature on the incubator. For a displayed skin temperature of 34 °C, the measured temperature should be between 33.7 °C and 34.3 °C. Repeat the temperature measurements at 36 °C and 38 °C.

Temperature alarms: Adjust the temperature set point on the warmer to its maximum setting. Place the sensor in the warmer and allow the temperature to stabilize. Remove the skin temperature sensor from the warmer and allow it to cool. Verify that the low temperature alarm activates. Place the skin temperature sensor back in the warmer and allow the temperature to stabilize. Hold the sensor close to the heater. Verify that the high temperature alarm activates.

Alarm function: Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

Unplug the temperature probe from the incubator. The disconnected probe alarm should activate. If the incubator is equipped with alarms for an open or short circuited temperature probe, use open and short circuited probe plugs to test these alarms. Disconnect the skin temperature probe and connect the probe plugs. The appropriate alarms should activate.

Unplug the incubator to simulate a power failure. The power failure alarm should activate.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any settings that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions. Plug in the power cord to ensure the battery remains charged.

Sphygmomanometer

A sphygmomanometer is a device for measuring blood pressure. It consists of an inflatable cuff, an inflation bulb with a one way valve, and a pressure meter. The pressure meter may be either a mercury manometer or an aneroid gauge, although many healthcare institutions no longer allow the use of mercury. Typically, the cuff is placed around the patient's arm and then inflated until the artery is occluded. The cuff is then deflated slowly while a clinician uses a stethoscope to listen for Korotkoff sounds, the sound of blood flow through the artery, at the brachial pulse. The pressure at which the first sound is heard as the cuff is deflating is the systolic pressure. The pressure at which sounds are no longer heard is the diastolic pressure.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	3
Device is used to deliver direct treatment to the patient	4	
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	2
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	3
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	1
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		10
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

Sphygmomanometer procedure

Estimated time: 5 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date:_____

Test type: Incoming _____ Post repair _____

Test equipment needed: DPM 4 Pressure Meter (or equivalent)
Stopwatch or watch with a second hand
Tubing and connectors to connect to DPM 4
PVC pipe to attach cuff to

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Preventive maintenance				
			Check condition of tubing, cuffs, and hoses	
			Complete model-specific preventive maintenance	
Performance testing				
			Gauge zero	± 1 mmHg
			Leak test	≤ 15 mmHg/min
			Pressure accuracy	± 3 mmHg
			Complete model-specific performance testing	

 ©University of Vermont, Rev. 2 – Confidential

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage.

Preventive maintenance

Check condition of tubing, cuffs, and hoses: Inspect hoses and cuffs for signs of wear. Look for holes, cracks, and dry rot. Ensure that all connections are secure.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Gauge zero: With no pressure in the cuff, read the pressure on the gauge of the sphygmomanometer. The gauge should read between –1 mmHg and 1 mmHg. Discard aneroid gauges that cannot be reset to zero.

Leak test: Place the cuff around a piece of PVC pipe or other sturdy cylindrical object to simulate placement on a limb. Connect a piece of tubing to the pressure port on the DPM 4. Connect a tee to this tubing and attach tubing and connectors. Connect the two legs of the tee to between the hose and the cuff of the sphygmomanometer. Close the bleed valve and use the cuff's squeeze ball to inflate the cuff to the maximum pressure indicated on the gauge. After 1 minute, read the pressure indicated on the gauge. The pressure should not have dropped more than 15mmHg in 1 minute.

Pressure accuracy: Inflate the cuff to until 200 mmHg is read on the DPM 4. Read the pressure on the sphygmomanometer gauge. The pressure on the gauge should be within 3 mmHg of the true pressure measured on the DPM 4. For a pressure of 200 mmHg, the gauge should read between 197 mmHg and 203 Hg. Repeat the pressure measurement for 120 mmHg and 60 mmHg.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any settings that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions. Plug in the power cord to ensure the battery remains charged.

Therapeutic stimulator

Therapeutic stimulators cause controlled muscular contractions by applying electrical stimuli to nerves that control muscle activity. They are typically used during physical therapy for pain management and to reduce swelling. These devices consist of a pulse generator, intensity controls, and a timer. A controlled electrical current is delivered to the muscles through electrodes applied to the patient's skin. Therapeutic stimulators are often used in conjunction with therapeutic ultrasound.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	4
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	3
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	
A significant history of incidents exists	2	2
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		12
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

 ©University of Vermont, Rev. 2 – Confidential

FLUKE®
Biomedical

Therapeutic stimulator procedure

Estimated time: 25 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
Oscilloscope such as Fluke 199XRAY
Stopwatch or watch with a second hand

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Inspect leads and electrodes	
			Complete model-specific preventive maintenance	
Performance testing				
			Output accuracy	± 10 %
			Timer accuracy	± 10 sec
			Alarm function	
			Complete model-specific performance testing	

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage.

Preventive maintenance

Inspect leads and electrodes: Inspect leads and electrodes for signs of wear such as frayed wires or broken strain reliefs. Inspect electrodes for corrosion or a build up of conductive gel. Clean if necessary.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection

Output accuracy: Connect the scope probe to channel A of the oscilloscope. Press the 'SCOPE' button on the 199XRAY to enter oscilloscope mode. Press the 'A' button on the scope to access the settings for channel A. Press the F3 ('PROBE A') and set the probe type to current. Connect the stimulator electrode cable to the scope probe. Set the simulator to a Russian waveform with a continuous cycle. Start the stimulator and adjust the output to 20 mA. Read the current measured on the scope. The measured current should be within 10 % of the set current. With a set current of 10 mA, the measured current should be between 9 mA and 11 mA. Repeat the measurement for 25 mA, 50 mA, and 100 mA.

Timer accuracy: Set the treatment timer on the stimulator for 1 minute. Start the stimulator and begin timing with a stopwatch or a watch with a second hand. The treatment timer should sound between 50 seconds and 70 seconds. Verify that the there is no output after the timer stops.

Alarm function: Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

Remove one of the electrode cables from the scope probe, being careful not to touch the exposed electrode. Verify that the electrode disconnection alarm activates.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any settings that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions.

Therapeutic ultrasound

Therapeutic ultrasounds deliver ultrasonic waves that penetrate tissues and cause thermal and non-thermal effects and are typically used to speed healing in soft tissue injuries. Energy from the sound waves is absorbed and causes heating in the tissue, resulting in an increase in blood flow, which speeds healing and reduces swelling. Sound waves also cause a cavitational effect from the vibration of the tissue, causing microscopic air bubbles to form. The air bubbles transmit the vibrations and stimulate cell membranes. Therapeutic ultrasounds consist of a radio frequency generator, usually 1 MHz to 3 MHz, an intensity controller, and an applicator containing a piezoelectric transducer.

Recommended functional test frequency: annual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	4
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	3
Device failure could result in severe injury to, or death of, patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	3
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	1
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		12
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

Therapeutic ultrasound procedure

Estimated time: 25 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
UW5 Ultrasound wattmeter (or equivalent)
Stopwatch or watch with a second hand

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Inspect sound head	
			Complete model-specific preventive maintenance	
Performance testing				
			Verify unit operates on battery	
			Output accuracy	± 20 %
			Duty cycle	
			Timer accuracy	± 10 sec
			Alarm function	
			Complete model-specific performance testing	

 ©University of Vermont, Rev. 2 – Confidential

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage.

Preventive maintenance

Inspect sound head: Inspect the sound head for signs of wear such as frayed wires or broken strain reliefs. Look for corrosion or a build up of conductive gel. Clean if necessary.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Measuring ultrasound power output with the UW5.

Performance inspection

Output accuracy: Ensure the UW5 is level before testing. If necessary, level the UW5 using the adjustable leveling jacks on the underside of the unit. Place the transducer cone on the mounting pin in the transducer well. Fill the transducer well with 850 ml ± 50 ml de-ionized and degassed water. The water should be at room temperature. Turn on the UW5 and allow at least 5 minutes for it to stabilize at room temperature. Press the 'ZERO' button to zero the wattmeter.

Place the appropriately sized centering ring over the transducer well. Place the sound head in the transducer well so that it is centered and vertical. The sound head should be completely coupled with water.

Start the ultrasound with a continuous duty cycle and bring the output to the maximum setting. Measure the ultrasound output on the UW5. The measured output should be within 20 % of the set output. For a set output of 20 W, the measured output should be between 16 W and 24 W. Repeat this measurement for all frequencies.

Duty cycle: Start an ultrasound treatment at 10 W and a continuous (100 %) duty cycle. The output on the UW5 should be approximately 10 W. Adjust the duty cycle to 50 %. The ultrasound output on the wattmeter should fall to 50 % of the output setting, or 5 W. Cycle through all of the available duty cycles and verify the output.

Timer accuracy: Set the treatment timer on the stimulator for 1 minute. Start the stimulator and begin timing with a stopwatch or a watch with a second hand. The treatment timer should sound between 50 seconds and 70 seconds. Verify that the there is no output after the timer stops.

Alarm function: Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

Disconnect the sound head cable from the ultrasound. Verify that the sound head disconnection alarm activates.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Remove the water from the transducer well of the UW5 when the measurements are complete. Using the drain tube located in the bottom front, completely drain the well. Remove the drain tube from its storage clip. Holding the tube end over a container, pinch the tube just in front of the stopper with one hand while pulling the stopper out with the other. Remove the stopper and allow the water to drain completely. The UW5 should be fully drained before being stored. This will prevent bacterial growth and other potential water related damage.

Return to service: Before returning to use, return any settings that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions.

Ventilator

Ventilators mechanically move air into and out of the lungs, to provide respiration for a patient who is physically unable to breathe, or is breathing insufficiently. Most ventilators use positive pressure to gas to the lungs. These devices typically consist of a breathing circuit, a control system, monitors, alarms, and a source of gas, either an internal compressor or external connections for compressed gas cylinders or the hospital gas wall outlets.

Recommended functional test frequency: semiannual.

Sample risk assessment

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	
Device is used for a life support	5	5
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	
Device failure could result in severe injury to, or death of, patient or user	4	4
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	4
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	
A significant history of incidents exists	2	2
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	
There are requirements for testing independent of a numerical rating system	2	2
Total Score:		17
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		2

Ventilator procedure

Estimated time: 50 minutes

Equipment information

Control number: _____ Hospital: _____

Manufacturer: _____ Model: _____

Serial number: _____ Location: _____

Test information

Technician: _____ Date: _____

Test type: Incoming _____ Post repair _____

Test equipment needed: ISA 601 Electrical Safety Analyzer (or equivalent)
VT PLUS HF Ventilator Analyzer (or equivalent)
Test lung (such as ACCULUNG)
Hoses and connectors to connect to VT PLUS HF

Test Result				
Pass	Fail	N/A		
Physical condition				
			Device is clean and decontaminated	
			No physical damage to case, display, mounts, cart, or components	
			Switches and controls operable and correctly aligned	
			Display intensity adequate for daytime use	
			Control numbers, labeling, and warnings present and legible	
			Inlets and hoses	
			Power cord, accessory cables, charger	
			Filters and vents clean	
Electrical safety				
			Ground wire resistance	< 0.3 Ω
			Chassis leakage	< 100 µA NC, < 500 µA SFC
			Patient leakage current	< 100 µA B and BF < 10 µA CF
			Patient lead leakage current – isolation test (mains on patient applied part)	< 100 µA BF < 10 µA CF
			Insulation test (optional) 500 V	< 2 MΩ
Preventive maintenance				
			Clean vents and filters	
			Replace tubing	
			Replace battery every 24 months	
			Complete model-specific preventive maintenance	

continued on page 143

 ©University of Vermont, Rev. 2 – Confidential

Ventilator procedure
Estimated time: 50 minutes

continued from page 142

Test Result				
Pass	Fail	N/A		
Performance testing				
			Verify unit operates on battery	
			Gas cylinders and regulators	
			Hoses, tubing, and connectors	
			Volume accuracy	± 10 %
			Respiration rate	
			I:E ratio	
			Pressure accuracy	± 10 %
			PEEP	
			O_2 accuracy	± 2 %
			Alarm function	
			Complete model-specific performance testing	

Physical condition

Check the physical condition of the device, as described in the General Equipment Procedure.

Electrical safety

Perform electrical safety checks as described in Chapter 5, Electrical Safety. Check ground wire resistance and chassis leakage.

Preventive maintenance

Clean vents and filters: Inspect vents and air filters. Clean or replace filters as necessary. Ensure that filters are installed properly.

Replace tubing: Replace internal tubing and filters as necessary. Follow the manufacturer's guidelines for tubing replacement.

Replace battery: The battery should be replaced every 24 months. Replace if necessary.

Complete model-specific preventive maintenance: Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

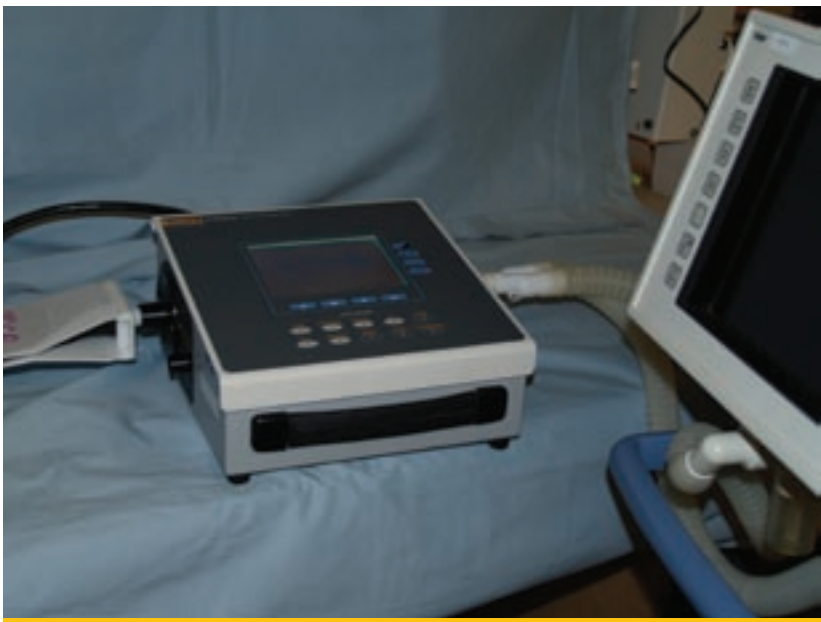
Performance inspection

Verify unit operates on battery: Check that the ac power indicator is lit when the power cord is plugged into an outlet. Unplug the ac power cord and perform the remainder of the functional test on battery power. The ac power indicator should go out when the power cord is unplugged and the battery indicator should light. Be sure to plug the power cord in at the conclusion of the test.

Gas cylinders and regulators: Check the condition of gas cylinders and regulators. Remove each cylinder and verify that the index pins are present on the cylinder yoke. Verify that cylinders have the correct color coding and labeling and that the cylinders are within their expiration dates. Replace the cylinders in their yokes. Disconnect hoses from the hospital's gas system. With the ventilator turned off, open each cylinder. Note the pressure in each cylinder. Replace any cylinders with less than 500 psi. Close the cylinders. The pressure should remain steady on the cylinder gauges.

Hoses, tubing, and connectors: Check the condition of external hoses, tubing, and connectors. Check for signs of wear such as cracking or dry rot. Ensure all connectors are tight.

Volume accuracy: Turn on the VT PLUS HF and allow it to warm up. Ensure that all hoses are disconnected from the analyzer and then press the soft key to zero the pressure and flow. Press '8' ('SETUP') on the analyzer to enter the setup menu. Use the arrow keys to highlight 'Gas Settings' and then press the 'MODIFY' soft key. Use the arrow keys to highlight 'GAS TYPE' and press the 'MODIFY' soft key to select the gas used in the ventilator. Most commonly, air or O_2 will be used. Enter the gas temperature, ambient temperature, and relative humidity of the gas as necessary. To change the settings,



Ventilator and test lung connected to the VT PLUS HF.

 ©University of Vermont, Rev. 2 – Confidential

highlight the parameter and then press the 'MODIFY' soft key. Enter the new value using the number keys on the front of the analyzer and then press the 'ENTER' soft key. Press the 'BACK' soft key to return to the measurement screen on the analyzer. Match the VT PLUS HF correction mode setting to that used by the ventilator manufacturer (usually found in the ventilator service manual).

Connect a patient breathing circuit to the ventilator. Connect the Y piece of the patient tubing to the high flow inlet on the right side of the VT PLUS HF analyzer. Set up the test lung (such as ACCULUNG) resistance and compliance settings by selecting a pair of resistance and compliance settings that most closely matches the patients served by the hospital owning the ventilator (e.g. resistance = Rp20, compliance = C20). Connect the test lung to the flow exhaust on the left side of the analyzer.

Enter the volume screen on the analyzer by pressing '2' ('VOLUME'). Set up the ventilator with a tidal volume of 200 mL, a breath rate of 25 breaths/min, and an inspiration to expiration ratio of 1:2 and start the ventilator. The ventilator may take a few breaths to stabilize the delivered volume. The measured volume should be within 10 % of the set volume. For a set tidal volume of 200 mL, the measured tidal volume should be between 180 mL and 220 mL. Repeat the measurement with a tidal volume of 1300 mL and a rate of 8 breaths/min. The tidal volume should be between 1170 mL and 1430 mL.

Respiration rate: Set up the VT PLUS HF analyzer and the ventilator as described above. The respiration rate can be read on the volume screen of the analyzer.

I:E ratio: Set up the VT PLUS HF analyzer and the ventilator as described above. The inspiration to expiration ratio can be read on the volume screen of the analyzer.

Pressure accuracy: Press '1' ('PRESSURE') on the VT PLUS HF to switch to the pressure screen. If the ventilator has a pressure control mode, enter a pressure of 40 cmH_20 and a rate of 6breaths/min, otherwise enter a tidal volume of 1000 mL and a rate of 6 breaths/min. Start the ventilator. Compare the pressure measured on the analyzer with the pressure displayed on the ventilator. The measured pressure should be within 10 % of the displayed pressure. For a displayed pressured of 40 cmH_20, the measured pressure should be between 36 cmH_20 and 44 cmH_20.

PEEP: Put the ventilator into volume control mode with a tidal volume of 1000 mL and a rate of 6 breaths/min. Begin ventilating. Watch the pressure airway pressure gauge during ventilation. Following expiration, the pressure gauge should return to zero. Set the PEEP (post expiratory end pressure) to 10 cmH_20. The airway pressure gauge should drop to 10 cmH_20 following expiration instead of returning to zero. Measure the actual PEEP using the VT PLUS HF. PEEP is displayed on the pressure screen.

O_2 accuracy: Before measuring oxygen concentration using VT PLUS HF, Ensure the sensor displays the oxygen concentration at 100 % O_2. If not, perform the oxygen calibration according to the VT PLUS HF operator's manual.

If possible, remove the O_2 sensor from the breathing circuit and allow the sensor to sit in room air for approximately 5 minutes. The O_2 reading in room air should be 21 %. Calibrate the sensor according to the ventilator manufacturer's recommended procedure if possible. Return the sensor to the breathing circuit. Set up the ventilator with a tidal volume of 1000 mL, a breath rate of 6 breaths/min, and an inspiration to expiration ratio of 1:2 and start the ventilator. Press '3' ('O_2') on the VT PLUS HF to switch to the O_2 screen. The O_2 percentage is displayed on the VT PLUS HF. Compare this value to the value displayed on the ventilator. The measured O_2 percentage should be within 2 digits of the displayed value. In 100 % O_2, the measured oxygen percentage should be at least 98 %.

Alarm function: Check that all alarms are functional and that the volume is adequately loud. Ensure that appropriate visual indicators are functioning.

Remove the O_2 sensor from the breathing circuit and expose it to room air. Set the low O_2 alarm to 30 %. Verify that the alarm activates. Return the O_2 sensor to the breathing system and return the alarm to its previous setting.

Close the O_2 cylinder and disconnect the pipeline. The low O_2 pressure alarm should activate. Reconnect the pipeline and clear the alarm. Repeat this for other gases if necessary.

Set up the ventilator with a tidal volume of 1000 mL, a rate of 6 breaths/min, and an I:E ratio of 1:2 and start the ventilator. Note the maximum airway pressure during ventilation. Set the high pressure limit about 10 cmH_2O below the peak inspiratory pressure. If the Peak inspiratory pressure is 40 cmH_2O, set the high pressure limit to 30 cmH_2O. Verify that the ventilator immediately stops delivering the breath when the pressure limit is reached and allows the breath to be exhaled. Verify that the alarm activates. Return the high alarm limit to its previous setting and clear the alarm.

Disconnect the inspiratory limb of the patient circuit from the ventilator. The low pressure alarm should activate.

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device. Complete the performance inspection per manufacturer's procedure.

Return to service: Before returning to use, return any settings that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal operating conditions. Plug in the power cord to ensure the battery remains charged. Standards are used to give a baseline

APPENDIX 1: Standards

performance that needs to be met in order to ensure the safe use of medical equipment. A medical equipment maintenance program needs to meet or exceed all local standards. All relevant standards should be reviewed to ensure program compliance. The following Chapter discusses some standards that biomedical personnel should be familiar with.

IEC 60601-1

The International Electrotechnical Commission, IEC, is a worldwide organization that promotes global standardization in the electronics industry. IEC 60601-1, titled *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, addresses the issues of safely designing medical equipment and serves as the foundation for safe manufacturing practices. This standard is mainly used in the design and manufacture of medical equipment.

In 2005, the third edition of 60601-1 was published. The object of the standard is to provide general requirements for safety of medical devices and to provide the basis for more specific standards. This edition combines product requirements with manufacturing processes such as risk management. This edition also addresses the concept of essential performance, parts of the equipment operation that directly affect the safety of the patient and operators.

The rationale behind the standard is to identify specific hazards associated with medical equipment and to define an acceptable level of risk for each hazard. Additionally, it provides an objective test to determine if the risks have been acceptably minimized, while avoiding requirements defining how to minimize risks.

This standard is not intended to be used alone, as it addresses general safety issues applied broadly across medical equipment. More specific standards need to be applied to specific types of medical equipment. The 60601 family of standards contains collateral and particular standards. Collateral standards contain requirements in addition to the parent standard. These standards are general in nature, like the parent standard, and are applicable to all medical equipment. Particular standards contain requirements that are exceptions to the parent and collateral standards. These types of standards are specific to a device type. IEC 60601 is the parent standard. Collateral standards are labeled as 60601-1-xx and particular standards are labeled as 60601-2-xx, with xx representing a specific document.

IEC 60601-1 is mainly used by manufacturers of medical equipment. Medical equipment that is manufactured to this standard has been subjected to rigorous safety and performance tests and has met quality assurance specifications.

IEC 62353

IEC 62353 is an international standard published by the International Electrotechnical Commission, a worldwide organization that promotes global standardization in the electronics industry. The standard deals with the testing of medical equipment before first use, after servicing, or periodic safety inspections.

The standard specifies how to test for electrical safety and gives limits for acceptable measurements. Specific tests for measuring the protective earth resistance, leakage current, applied part leakage current, and insulation resistance are outlined. These terms are defined as:

Protective earth resistance: Sometimes referred to as ground wire resistance. Resistance between any conductive part of the equipment and the protective connector of the main power supply plug, the protective connector of the appliance inlet, or the protective conductor permanently connected to the supply mains.

Equipment leakage current: Current flowing from the supply mains to earth through the protective earth conductor and accessible conductive parts.

Applied part leakage current: Sometimes referred to as lead leakage. The current flowing from the supply mains and accessible conductive parts to the applied parts, or patient leads.

Insulation resistance: The resistance of the insulation between the supply mains and protective earth, the supply mains and accessible conductive parts, or the supply mains and the patient leads. The insulation resistance is calculated by applying a voltage and measuring the resulting current.

IEC 62353 sets specific limits for electrical safety testing. The protective earth resistance should not exceed 300 mΩ. Leakage current for Class I medical equipment should not exceed 500 µA using the direct measurement method; leakage current for Class II medical equipment should not exceed 100 µA.

Electrical safety testing is discussed in detail in Chapter 5 of this manual, Electrical Safety. IEC 62353 goes on to further specify that safety related functions of the equipment are to be inspected. The standard does not specify which functions need to be tested or how often, only that the device functionality should be tested. The standard also specifies that safety inspections need to be documented.

NFPA 99

The National Fire Protection Agency is an international organization that advocates the consensus of codes and standards for fire, electrical, and building safety. NFPA building codes have been adopted in the United States. The standard NFPA 99, *Standard for Health Care Facilities*, establishes criteria to minimize the risk of fire, explosion, and electrical hazards in health care facilities.

NFPA 99 covers nearly all aspects of fire safety in the hospital environment including building electrical systems, vacuum and gas systems, and emergency management. It is important to note that this is a voluntary standard. However, many localities have adopted NFPA 99 as part of their fire codes.

NFPA 99 includes a Chapter on electrical equipment that is of particular interest to biomedical equipment technicians. This Chapter specifically covers the performance, maintenance, and testing of electrical equipment used within the hospital. Numerical criteria are given for electrical safety testing. NFPA 99 section 8.4 states that the ground wire resistance of medical equipment should be less than 0.5 Ω. It goes on to say that the chassis leakage current should not exceed 300 µA.

The Joint Commission

The Joint Commission is a regulatory body that evaluates and accredits health care organizations in the United States. The Joint Commission's mission is to improve the safety and quality of healthcare provided to the public. Currently, a system of unannounced surveys is used to promote continued compliance of the Joint Commission's regulations.

The Joint Commission releases National Patient Safety Goals annually relating to pertinent healthcare quality issues. The National Patient Safety Goals are eventually rolled into the Joint Commission's regulations. The Joint Commission's regulations include a Chapter on the Environment of Care. This Chapter specifically deals with medical equipment, its maintenance, and how to minimize its risk. One common benchmark that is used in the United States is the completion of scheduled maintenance. The Joint Commission requires that 100 % of life support equipment receive its scheduled maintenance and that at least 90 % of non-life support equipment receive its scheduled maintenance.

FLUKE®
Biomedical

Author's biographical information

J. Tobey Clark, MSEE CCE, is the Director, Instrumentation and Technical Service, at the University of Vermont. He leads the **Technical Services Program**, a 26 hospital shared service clinical engineering program serving Vermont, upstate New York, and northern New Hampshire. Tobey also directs the **Instrumentation & Model Facility (IMF)** which designs, develops, fabricates and services custom research instruments for the University of Vermont community. He has a faculty appointment in the **School of Engineering** and the **College of Nursing and Health Sciences** where he teaches medical instrumentation courses. Tobey is involved in a number of professional activities including serving as a board member of the **ACCE Healthcare Technology Foundation** and as an advisor to the World and Pan American Health Organizations. He was the 2002 recipient of the *Clinical/Biomedical Engineering Career Achievement* award from the **Association for the Advancement of Medical Instrumentation** and the 2008 *Professional Achievement in Management* award from the **American College of Clinical Engineering**. Tobey is currently supported by several grants related to medical technology education and international clinical engineering exchange.

Michael W. Lane, MBA, is the Associate Director, Instrumentation and Technical Services, at the University of Vermont. He manages the operations of **Technical Services Program**, a 26 hospital shared service clinical engineering program serving Vermont, upstate New York, and northern New Hampshire. He holds Certification as a Quality Manager from the **American Society for Quality**. Michael is a member of the Vermont Council for Quality and serves as a state examiner for Performance Excellence. Michael is a member of the Association for the **Advancement of Medical Instrumentation** and of the **American Society for Field Service Managers**.

Leah Rafuse, BSME, is a clinical engineer with **Technical Services Program**, a 26 hospital shared service clinical engineering Program, at the University of Vermont. Leah is responsible for clinical engineering services for eight hospitals in upstate New York. Leah is a graduate of the University of Vermont's engineering program. Prior to taking over clinical engineering services in New York, Leah worked with Technical Services Program as a biomedical equipment technician, specializing in anesthesia equipment.

FLUKE®

Biomedical

©2009 Fluke Biomedical.
1/2009 3276553 C-EN-N Rev A